(ii) Paragraph (c)(2), to provide handwashing and toilet facilities, by July 30, 1987;

(iii) Paragraph (c)(3), to provide maintenance for toilet and handwashing facilities, by July 30, 1987; and

(iv) Paragraph (c)(4), to assure reasonable use, by July 30, 1987.

[FR Doc. 87-9842 Filed 4-28-87; 2:00 pm]

BILLING CODE 4510-26-M

federal register

Friday
May 1, 1987

Part V

Environmental Protection Agency

Industrial Biotest Laboratories, Inc.; Disposal of Raw Materials; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00237; FRL-3194-6]

Industrial Biotest Laboratories, Inc.; Disposal of Raw Materials

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This is a notice to certain persons who sponsored laboratory studies that were conducted by Industrial Biotest Inc. (IBT) and submitted such IBT studies to EPA and the Food and Drug Administration (FDA) in connection with information requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Raw materials relating to these IBT studies have been in the possession of the Federal Government in connection with *U.S.* v. *Keplinger, et al.* This case has been concluded, and submitters of these IBT studies have been notified to take possession of the raw materials that relate to these studies. Raw materials that have not been claimed by study sponsors have been stored at EPA since June 1985. Since these raw materials are no longer needed by the Federal Government, and have not been claimed by the sponsoring persons, EPA intends to discontinue storage by disposing of all unclaimed raw materials.

DATE: Unclaimed raw materials relating to IBT studies that were submitted to EPA and/or FDA to satisfy FIFRA or FFDCA pesticide information requirements will be disposed of on or about May 15, 1987.

FOR FURTHER INFORMATION CONTACT: By Mail: William C. Grosse, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 222, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-2613).

SUPPLEMENTARY INFORMATION: Raw materials to which this notice applies consist of paraffin tissue blocks and slides of tissues cut for microscopic examination. Tissue samples involved were taken during the approximate period of 1968 to 1976.

Sponsors of IBT studies were notified individually by letter from IBT during the period of April to July 1984 to contact IBT if they wished to retrieve their study raw materials at IBT's Northbrook, IL facility, and that otherwise the study raw materials would be disposed of. The IBT letters also advised study sponsors that EPA believed, based on 40 CFR 169.2(k) and sections 8 and 12(a)(2)(B) of FIFRA, that study sponsors should maintain the slides and tissue blocks as if they were specifically covered by recent EPA Good Laboratory Practices, 48 FR 53946 (November 29, 1983; effective May 2, 1984) until EPA informed them that these materials are no longer pertinent to the registration of any pesticide product. The IBT letters also advised that FDA recommends retention of these materials on studies which sponsors intended to validate or had successfully validated to the satisfaction of FDA. EPA believes that IBT study sponsors have received adequate notice that they could retrieve their study raw materials, and that no useful purpose can be served by storing these materials in the future. Hence, these materials will not be retained by the Government.

Dated: April 28, 1987.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 87-9973 Filed 4-30-87; 8:45 am]

BILLING CODE 6560-50-M

federal register

Friday
May 1, 1987

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 862

Clinical Chemistry and Toxicology Devices—General Provisions and Classifications and Premarket Notification Exemptions; Final, and Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 78N-2285]

Clinical Chemistry and Clinical Toxicology Devices; General Provisions and Classifications of 220 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 220 clinical chemistry and clinical toxicology devices. The preamble to this rule responds to comments received on the proposed regulations regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

DATES: This final rule will become effective on July 30, 1987. Comments by June 30, 1987 regarding the regulations for those devices whose classifications in the final rule are different from their proposed classifications.

ADDRESS: Written comments to the Dockets Mangement Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION: .

Table of Contents

A. Background

In the **Federal Register** of February 2, 1982 (47 FR 4802), FDA published a proposed rule containing general provisions applicable to the classification of clinical chemistry and clinical toxicology devices and individual proposed regulations to classify clinical chemistry and clinical toxicology devices in commercial distribution into one of two regulatory classes: class I (general controls) and class II (performance standards). The agency did not propose any regulations to classify clinical chemistry devices or clinical toxicology devices into class III (premarket approval).

In this final rule, FDA is classifying 220 clinical chemistry and clinical toxicology devices.

FDA is classifying 138 devices into class I and 82 devices into class II. Of the 138 class I devices, 31 were proposed for class I, while 106 were proosed for class II. (The one remaining class I device was the subject of a reclassification petition, as discussed below.) Neither the proposal nor the final rule has placed any preamendments devices in class III. However, FDA is codifying the statutory classification of one postamendments device into class III. (see paragraph 25).

The decision to classify into class I many devices that FDA proposed to classify into class II is based on FDA's consideration of the 3,000 comments on the proposed rule, many of which urged that all or most clinical chemistry and clinical toxicology devices be classified into class I. As a result of these comments, FDA reconsidered its proposed classification for each of the devices included in the 1982 proposal and, to evaluate the comments, reviewed relevant scientific literature. The literature confirmed that, for many devices, the comments were correct in their contention that the devices should be classified into class I rather than class II.

FDA has concluded that the agency may legally publish a final rule classifying clinical chemistry and clinical toxicology devices (*see AFL-CIO* v. *Marshall*, 617 F.2d 636, 676 (D.C. Cir. 1979)). The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposal or after reconsideration, the agency may determine that its proposed classification is incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general provisions for clinical chemistry and clinical toxicology devices (see 47 FR 4804; February 2, 1982). However, because of the large number of devices that are being classified differently than was proposed in part because of new scientific literature (see the reference list at the end of this preamble), FDA is allowing interested persons to comment on the regulations for those devices whose classifications in the final rule are different from their proposed classifications by June 30, 1987.

If FDA decides on the basis of the comments received that any changes in the final rule are necessary, it will publish those changes in the **Federal Register.**

Among the 220 devices being classified are 14 devices that were reclassified into class I (1 device) or class II (13 devices) in response to 19 reclassification petitions on postamendments clinical chemistry and clinical toxicology devices. Fourteen rather than 19 codifications are announced in response to the petitions because two petitions described the same type of device and four petitions related to devices adequately described by provisions in the clinical chemistry and clinical toxicology classification proposal of February 2, 1982. For a further discussion of these petitions and FDA's actions on the petitions, see the discussion at the end of the preamble under "H. Reclassification of Devices." Thus, in this final rule FDA is classifying 220 devices.

Elsewhere in this issue of the **Federal Register,** FDA is proposing to grant an exemption from the requirement of premarket notification for each of 21 class I clinical chemistry and clinical toxicology devices.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 302-392). The effect of classifying a device in class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device in class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments (postamendments devices), are

classified by statute into class III and already are required to have in effect an approved application for premarket approval. (see sections 520(l) and 513(f) of the act (21 U.S.C. 360j(l) and 360c(f)).

The preamble to the proposed rule described the development of the general provisions and the proposed regulations classifying clinical chemistry and clinical toxicology devices and the activities of the Clinical Chemistry and Clinical Toxicology Devices Panel (formerly the Clinical Chemistry and Hematology Devices Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of clinical chemistry and clinical toxicology devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. FDA subsequently extended the period by 120 days, to September 1, 1982 (see 47 FR 11879; March 19, 1982). The comments received and FDA's responses are discussed below.

In April 1985, H.R. 2177 (99th Cong. 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) made the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards set out in section 514 of the act. If legislation comparable to this bill becomes law, there will be only two categories of devices, class I (general controls) and class II (premarket approval, formerly class III). Class II devices would be redesignated as class I devices. Because this legislation includes transitional provisions that translate classifications under the current law to classifications under the proposed law, FDA is continuing its issuance of classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the Federal Register of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II.

In the October 23, 1985, notice, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices:

1. The seriousness of questions concerning the safety and effectiveness of the device; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device.
2. The recommendations of FDA's advisory committees.
3. The impact of an FDA guideline or recommendation.
4. The effect of a Federal standard or other regulatory controls under an authority other than the act.
5. The impact of voluntary standards.
6. The impact of activities authorized under the general controls provisions of the act.
7. The effect of dissemination of information and education efforts.
8. The sufficiency of voluntary corrective actions.
9. Valid scientific evidence developed since classification.
10. The existence of a petition for reclassification.
11. The impact of any other factors that affect a device's safety or effectiveness.

C. Chances in the Name of the Clinical Chemistry and Clinical Toxicology Devices Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently on April 14, 1984, FDA terminated the Clinical Chemistry and Hematology Devices Panel and its sections and established several new committees, including the Clinical Chemistry and Clinical Toxicology Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to clinical chemistry and clinical toxicology devices as did its predecessors, the Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel (1976–1978) and the Clinical Chemistry and Hematology Devices Panel (1978–1984).

D. Changes in Classification of Devices

As discussed above, based upon the comments received and on additional consideration of all information before the agency, FDA has classified 106 devices into class I that were the subject of proposals to classify the devices into class II. The names of devices that are being classified differently from the proposals are identified with asterisks (*) in the listing of devices under "E. List of Clinical Chemistry and Clinical Toxicology Devices." The reasons for these changes are identified in the preamble under "F. Summaries of Comments and FDA's Responses to Comments." As discussed above, FDA does not believe that it is necessary to issue new proposals concerning these changes.

Occasionally, the agency has made minor changes in device names or identifications to clarify the final regulations. Additionally, the agency has corrected typographical errors that were made in a number of proposed regulations.

E. List of Clinical Chemistry and Clinical Toxicology Devices

A list of clinical chemistry and clinical toxicology devices follows. The list shows the section of the Code of Federal Regulations at which the device classification is being codified, the docket number of any proposed classification regulation, the classification of each device, a statement (yes or no) whether public comments were received on the proposed classification regulation, and asterisks for devices that are being classified differently than was proposed.

The list also identifies the 21 generic types of clinical chemistry and clinical toxicology devices that are subjects of a proposed rule published elsewhere in this issue of the Federal Register. In that proposed rule, FDA is proposing to grant to manufacturers of each of the 21 class I devices an exemption from the requirement of premarket notification with respect to these devices. The name of each of the 21 devices is identified with footnote "[2]" (§ § 862.1190, 862.1210, 862.1255, 862.1290, 862.1305, 862.1320, 862.1365, 862.1380, 862.1420, 862.1470, 862.1490, 862.1515, 862.1565, 862.1575, 862.1640, 862.1670, 862.1720, 862.1815, 862.2100, 862.3750, and 862.3850).

SUBPART B—CLINICAL CHEMISTRY TEST SYSTEMS

Section	Device	Docket number	Class	Comment
862.1020	Acid Phosphatase (total or prostatic test system)	78N-2287	II	Yes.
862.1025	Adrenocorticotropic hormone (ACTH) test system	78N-2288	II	Yes.
862.1030	Alanine amino transferase (ALT/SGPT) test system*	78N-2289	I	Yes.
862.1035	Albumin test system	78N-2290	II	Yes.
862.1040	Aldolase test system*	78N-2291	I	Yes.
862.1045	Aldosterone test system	78N-2292	II	Yes.
862.1050	Alkaline phosphatase or isoenzymes test system	78N-2293	II	Yes.
862.1060	Delta-aminolevulinic acid test system*	78N-2295	I	Yes.
862.1065	Ammonia test system*	78N-2296	I	Yes.
862.1070	Amylase test system	78N-2297	II	Yes.
862.1075	Androstenedione test system*	78N-2298	I	Yes.
862.1080	Androsterone test system*	78N-2299	I	Yes.
862.1085	Angiotensin I and renin test system	78N-2300	II	Yes.
862.1090	Angiotensin converting enzyme test (A.C.E.) system[1]	77N-0394	II	
862.1095	Ascorbic acid test system*	78N-2301	I	Yes.
862.1100	Aspartate amino transferase (AST/SGOT) test system	78N-2302	II	Yes.
862.1110	Bilirubin (total or direct) test system	78N-2303	II	Yes.
862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system*	78N-2304	I	Yes.
862.1120	Blood gases (P_{CO} $2P_0$ 2) and blood pH test system	78N-2305	II	Yes.
862.1130	Blood volume test system*	78N-2307	I	Yes.
862.1135	C-Peptides of pro-insulin test system*	78N-2308	I	Yes.
862.1140	Calcitonin test system	78N-2309	II	Yes.
862.1145	Calcium test system	78N-2310	II	Yes.
862.1150	Calibrator	78N-2311	II	Yes.
862.1155	Human chorionic gonadotropin (HCG) test system	78N-2312	II, III	Yes.
862.1160	Bicarbonate/carbon dioxide test system	78N-2313	II	Yes.
862.1165	Catecholamines (total) test system*	78N-2314	I	Yes.
862.1170	Chloride test system	78N-2315	II	Yes.
862.1175	Cholesterol (total) test system*	78N-2316	I	Yes.
862.1177	Cholylglycine test system[1]	78P-0058	II	
862.1180	Chymotrypsin test system*	78N-2317	I	Yes.
862.1185	Compound S (11-deoxycortisol) test system*	78N-2318	I	Yes.
862.1187	Conjugated sulfolithocholic acid (SLCG) test system[1]	78N-0185	II	
862.1190	Copper test system* [2]	78N-2319	I	Yes.
862.1195	Corticoids test system*	78N-2320	I	Yes.
862.1200	Corticosterone test system*	78N-2321	I	Yes.
862.1205	Cortisol (hydrocortisone and hydroxycorticosterone) test system	78N-2322	II	Yes.
862.1210	Creatine test system* [2]	78N-2323	I	Yes.
862.1215	Creatine phosphokinase/creatine kinase or isoenzymes test system	78N-2324	II	Yes.
862.1225	Creatinine test system	78N-2326	II	Yes.
862.1230	Cyclic AMP test system	78N-2327	II	Yes.
862.1240	Cystine test system*	78N-2329	I	Yes.
862.1245	Dehydroepiandrosterone (free and sulfate) test system*	78N-2330	I	Yes.
862.1250	Desoxycorticosterone test system*	78N-2331	I	Yes.
862.1255	2,3-Diphosphoglyceric acid test system* [2]	78N-2332	I	Yes.
862.1260	Estradiol test system*	78N-2333	I	Yes.
862.1265	Estriol test system*	78N-2334	I	Yes.
862.1270	Estrogens (total in pregnancy) test system*	78N-2335	I	Yes.
862.1275	Estrogens (total, nonpregnancy) test system*	78N-2336	I	Yes.
862.1280	Estrone test system*	78N-2337	I	Yes.
862.1285	Etiocholanolone test system*	78N-2338	I	Yes.
862.1290	Fatty acids test system* [2]	78N-2339	I	Yes.
862.1295	Folic acid test system	78N-2340	II	Yes.
862.1300	Follicle-stimulating hormone test system*	78N-2341	I	Yes.
862.1305	Formiminoglutamic acid (FIGLU) test system* [2]	78N-2342	I	Yes.
862.1310	Galactose test system*	78N-2343	I	Yes.
862.1315	Galactose-1 phosphate uridyl transferase test system	78N-2344	II	Yes.
862.1320	Gastric acidity test system* [2]	78N-2345	I	Yes.
862.1325	Gastrin test system*	78N-2346	I	Yes.
862.1330	Globulin test system*	78N-2347	I	Yes.
862.1335	Glucagon test system*	78N-2348	I	Yes.
862.1340	Urinary glucose (nonquantitative) test system	78N-2349	II	Yes.
862.1345	Glucose test system	78N-2350	II	Yes.
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system*	78N-2353	I	Yes.
862.1365	Glutathione test system* [2]	78N-2354	I	Yes.
862.1370	Human growth hormone test system*	78N-2355	I	Yes.
862.1375	Histidine test system*	78N-2356	I	Yes.
862.1377	Urinary homocystine (nonquantitative) test system[1]	80P-0510	II	
862.1380	Hydroxybutyric dehydrogenase test system* [2]	78N-2357	I	Yes.
862.1385	17-Hydroxycortico-steroids (17-ketogenic steroids) test system*	78N-2358	I	Yes.
862.1390	5-Hydroxyindole acetic acid/serotonin test system*	78N-2359	I	Yes.

SUBPART B—CLINICAL CHEMISTRY TEST SYSTEMS—Continued

Section	Device	Docket number	Class	Comment
862.1395	17-Hydroxyprogesterone test system*	78N-2360	I	Yes.
862.1400	Hydroxyproline test system*	78N-2361	I	Yes.
862.1405	Immunoreactive insulin test sytem*	78N-2362	I	Yes.
862.1410	Iron (non-heme) test system*	78N-2363	I	Yes.
862.1415	Iron-binding capacity test system*	78N-2364	I	Yes.
862.1420	Isocitric dehydrogenase test system* [2]	78N-2365	I	Yes.
862.1430	17-Ketosteroids test system*	78N-2367	I	Yes.
862.1435	Ketones (non-quantitative) test system*	78N-2368	I	Yes.
862.1440	Lactate dehydrogenase test system	78N-2369	II	Yes.
862.1445	Lactate dehydrogenase isoenzymes test system	78N-2370	II	Yes.
862.1450	Lactic acid test system*	78N-2371	I	Yes.
862.1455	Lecithin/sphingomyelin ratio in amniotic fluid test system	78N-2372	II	Yes.
862.1460	Leucine aminopeptidase test system*	78N-2373	I	Yes.
862.1465	Lipase test system*	78N-2374	I	Yes.
862.1470	Lipid (total) test system* [2]	78N-2375	I	Yes.
862.1475	Lipoprotein test system*	78N-2376	I	Yes.
862.1485	Luteinizing hormone test system*	78N-2378	I	Yes.
862.1490	Lysozyme (muramidase) test system* [2]	78N-2379	I	Yes.
862.1495	Magnesium test system*	78N-2380	I	Yes.
862.1500	Malic dehydrogenase test system*	78N-2381	I	Yes.
862.1505	Mucopolysaccharides (nonquantitative) test system*	78N-2382	I	Yes.
862.1509	Methylmalonic acid (nonquantitative) test system[1]	80P-0511	II	
862.1510	Nitrite (nonquantitative) test system*	78N-2383	I	Yes.
862.1515	Nitrogen (aminonitrogen) test system* [2]	78N-2384	I	Yes.
862.1520	5'-Nucleotidase test system*	78N-2385	I	Yes.
862.1530	Plasma oncometry test system*	78N-2387	I	Yes.
862.1535	Ornithine carbamyl transferase test system*	78N-2388	I	Yes.
862.1540	Osmolality test system*	78N-2389	I	Yes.
862.1542	Oxalate test system[1]	84P-0212	I	
862.1545	Parathyroid hormone test system	78N-2390	II	Yes.
862.1550	Urinary pH (nonquantitative) test system*	78N-2391	I	Yes.
862.1555	Phenylalanine test system	78N-2392	II	Yes.
862.1560	Urinary phenylketones (nonquantitative) test system*	78N-2393	I	Yes.
862.1565	6-Phosphogluconate dehydrogenase test system* [2]	78N-2394	I	Yes.
862.1570	Phosphohexose isomerase test system*	78N-2395	I	Yes.
862.1575	Phospholipids test system* [2]	78N-2396	I	Yes.
862.1580	Phosphorus (inorganic) test system*	78N-2397	I	Yes.
862.1585	Human placental lactogen test system	78N-2398	II	Yes.
862.1590	Porphobilinogen test system*	78N-2399	I	Yes.
862.1595	Porphyrins test system*	78N-2400	I	Yes.
862.1600	Potassium test system	78N-2401	II	Yes.
862.1605	Pregnanediol test system*	78N-2402	I	Yes.
862.1610	Pregnanetriol test system*	78N-2403	I	Yes.
862.1615	Pregnenolone test system*	78N-2404	I	Yes.
862.1620	Progesterone test system*	78N-2405	I	Yes.
862.1625	Prolactin (lactogen) test system*	78N-2406	I	Yes.
862.1630	Protein (fractionation) test system*	78N-2407	I	Yes.
862.1635	Total protein test system	78N-2408	II	Yes.
862.1640	Protein-bound iodine test system* [2]	78N-2409	I	Yes.
862.1645	Urinary protein or albumin (nonquantitative) test system*	78N-2410	I	Yes.
862.1650	Pyruvate kinase test system*	78N-2411	I	Yes.
862.1655	Pyruvic acid test system*	78N-2412	I	Yes.
862.1660	Quality control material (assayed and unassayed)	78N-2413	I	Yes.
862.1665	Sodium test system	78N-2414	II	Yes.
862.1670	Sorbitol dehydrogenase test system* [2]	78N-2415	I	Yes.
862.1675	Blood specimen collection device	78N-2416	II	Yes.
862.1680	Testosterone test system*	78N-2417	I	Yes.
862.1685	Thyroxine-binding globulin test system	78N-2418	II	Yes.
862.1690	Thyroid-stimulating hormone test system	78N-2419	II	Yes.
862.1695	Free thyroxine test system	78N-2420	II	Yes.
862.1700	Total thyroxine test system	78N-2421	II	Yes.
862.1705	Triglyceride test system*	78N-2422	I	Yes.
862.1710	Total triiodothyronine test system	78N-2423	II	Yes.
862.1715	Triiodothyronine uptake test system	78N-2424	II	Yes.
862.1720	Triose phosphate isomerase test system* [2]	78N-2425	I	Yes.
862.1725	Trypsin test system*	78N-2426	I	Yes.
862.1730	Free tryosine test system*	78N-2427	I	Yes.
862.1770	Urea nitrogen test	78N-2428	II	Yes.
862.1775	Uric acid test system*	78N-2429	I	Yes.
862.1780	Urinary calculi (stone) test system*	78N-2430	I	Yes.
862.1785	Urinary urbilinogen (nonquantitative) test system*	78N-2431	I	Yes.

SUBPART B—CLINICAL CHEMISTRY TEST SYSTEMS—Continued

Section	Device	Docket number	Class	Comment
862.1790	Uroporphyrin test system*	78N-2432	I	Yes.
862.1795	Vanilmandelic acid test system*	78N-2433	I	Yes.
862.1805	Vitamin A test system*	78N-2435	I	Yes.
862.1810	Vitamin B^{12} test system	78N-2436	II	Yes.
862.1815	Vitamin E test system*	78N-2437	I	Yes.
862.1820	Xylose test system*	78N-2438	I	Yes.

[1] Not proposed; classification results from a reclassification petition. See the discussion at the end of the preamble, "H. Reclassification of Devices."

[2] The device is subject of a proposed rule published elsewhere in this issue of the FEDERAL REGISTER to grant manufacturers an exemption from premarket notification with respect to these devices.

SUBPART C—CLINICAL LABORATORY INSTRUMENTS

Section	Device	Docket No.	Class	Comment
862.2050	General purpose laboratory equipment labeled or promoted for a specific medical use.	78N-2439	I	Yes.
862.2100	Calculator/data processing module for clinical use [2]	78N-2441	I	Yes.
862.2140	Centrifugal chemistry analyzer for clinical use	78N-2443	I	No.
862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use.	78N-2444	I	No.
862.2160	Discrete photometric chemistry analyzer for clinical use	78N-2445	I	No.
862.2170	Micro chemistry analyzer for clinical use	78N-2446	I	No.
862.2230	Chromatographic separation material for clinical use	78N-2450	I	No.
862.2250	Gas liquid chromatography system for clinical use	78N-2452	I	No.
862.2260	High-pressure liquid chromatography system for clinical use	78N-2453	I	No.
862.2270	Thin-layer chromatography system	78N-2454	I	No.
862.2300	Colorimeter, photometer, or spectrophotometer for clinical use	78N-2455	I	Yes.
862.2310	Clinical sample concentrator	78N-2456	I	No.
862.2320	Beta or gamma counter for clinical use	78N-2457	I	No.
862.2400	Densitometer/scanner (integrating, reflectance, TLC or radiochromatogram) for clinical use.	78N-2459	I	No.
862.2485	Electrophoresis apparatus for clinical use	78N-2463	I	No.
862.2500	Enzyme analyzer for clinical use	78N-2464	I	No.
862.2540	Flame emission photometer for clinical use	78N-2467	I	No.
862.2560	Fluorometer for clinical use	78N-2468	I	No.
862.2680	Microtitrator for clinical use	78N-2472	I	No.
862.2700	Nephelometer for clinical use	78N-2474	I	No.
862.2720	Plasma oncometer for clinical use	78N-2475	I	No.
862.2730	Osmometer for clinical use	78N-2476	I	No.
862.2750	Pipetting and diluting system for clinical use	78N-2477	I	No.
862.2800	Refractometer for clinical use	78N-2481	I	Yes.
862.2850	Atomic absorption spectrophotometer for clinical use	78N-2483	I	Yes.
862.2860	Mass spectrometer for clinical use	78N-2484	I	Yes.
862.2900	Automated urinalysis system	78N-2487	I	No.
862.2920	Plasma viscometer for clinical use	78N-2488	I	No.

[2] The device is subject of a proposed rule published elsewhere in this issue of the FEDERAL REGISTER to grant manufacturers an exemption from premarket notification with respect to these devices.

SUBPART D—CLINCAL TOXICOLOGY TEST SYSTEM

Section	Device	Docket Number	Class	Comment
862.3030	Acetaminophen test system [1]	79P-0317	II	
862.3035	Amikacin test system [1]	77P-0338 and 77P-0342	II	
862.3040	Alcohol test system	78N-2490	II	Yes.
862.3050	Breath-alcohol test system	78N-2491	I	No.
862.3100	Ampehtamine test system	78N-2495	II	Yes.
862.3110	Antimony test system*	78N-2496	I	Yes.
862.3120	Arsenic test system*	78N-2497	I	Yes.
862.3150	Barbiturate test system	78N-2498	II	Yes.
862.3170	Benzodiazepine test system	78N-2499	II	Yes.
862.3200	Clinical toxicology calibrator	78N-2501	II	Yes.
862.3220	Carbon monoxide test system*	78N-2503	I	Yes.
862.3240	Cholinesterase test system*	78N-2505	I	Yes.
862.3250	Cocaine and cocaine metabolite test system	78N-2506	II	Yes.
862.3270	Codeine test system	78N-2508	II	Yes.
862.3280	Clinical toxicology control material	78N-2509	I	No.

SUBPART D—CLINCAL TOXICOLOGY TEST SYSTEM—Continued

Section	Device	Docket Number	Class	Comment
862.3300	Digitoxin test system	78N-2511	II	Yes.
862.3320	Digoxin test system	78N-2513	II	Yes.
862.3350	Diphenylhydantoin test system	78N-2515	II	Yes.
862.3380	Ethosuximide test system	78N-2516	II	Yes.
862.3450	Gentamicin test system	78N-2518	II	Yes.
862.3520	Kanamycin test system	78N-2522	II	Yes.
862.3550	Lead test system	78N-2523	II	Yes.
862.3555	Lidocaine test system [1]	78P-0341	II	
862.3560	Lithium test system	78N-2377	II	Yes.
862.3580	Lysergic acid diethylamide (LSD) test system	78N-2526	II	Yes.
862.3600	Mercury test system*	78N-2527	I	Yes.
862.3610	Methamphetamine test system	78N-2528	II	Yes.
862.3620	Methadone test system	78N-2529	II	Yes.
862.3630	Methaqualone test system [1]	77P-0052	II	
862.3640	Morphine test system	78N-2531	II	Yes.
862.3645	Neuroleptic drugs radioreceptor assay test system [1]	82P-0263	II	
862.3650	Opiate test system	78N-2532	II	Yes.
862.3660	Phenobarbital test system	78N-2533	II	Yes.
862.3670	Phenothiazine test system	78N-2534	II	Yes.
862.3680	Primidone test system	78N-2535	II	Yes.
862.3700	Propoxyphene test system	78N-2537	II	Yes.
862.3750	Quinine test system [1]	78N-2540	I	Yes.
862.3830	Salicylate test system	78N-2541	II	Yes.
862.3850	Sulfonamide test system [1]	78N-2542	I	Yes.
862.3870	Cannabinoid test system	78N-2543	II	Yes.
862.3880	Theophylline test system [1]	77P-0340	II	
862.3900	Tobramycin test system	78N-2545	II	Yes.
862.3910	Tricyclic antidepressant drugs test system [1]	79P-0091	II	
862.3950	Vancomycin test system [2]	80P-0142	II	

[1] Not proposed; classification results from a reclassification petition. See the discussion at the end of the preamble, "H. Reclassification of Devices.

[2] The device is subject of a proposed rule published elsewhere in this issue of the Federal Register to grant manufacturers an exemption from premarket notification with respect to these devices.

F. Summaries of Comments and FDA's Responses to Comments

FDA received about 3,000 comments from the public on the 206 proposed regulations, and about 90 percent of the comments requested that most of the 175 clinical chemistry and clinical toxicology devices that FDA proposed to be in class II be classified instead into class I. Most comments agreed with FDA's proposed classification of 31 devices into class I, and in the final rule all 31 devices are classified into class I as proposed.

In response to comments and upon its own reconsideration, FDA is classifying 106 clinical chemistry and clinical toxicology devices into class I instead of class II as proposed. FDA also is classifying 69 clinical chemistry and clinical toxicology devices into class II as proposed, where neither comments nor further consideration by FDA demonstrated that the agency's proposed classification for these devices was incorrect. Each name of a generic type of device that is being classified differently than was proposed is identified with an asterisk (*) in the list of devices under "E. List of Clinical Chemistry and Clinical Toxicology Devices."

The many comments arguing that most clinical chemistry and clinical toxicology devices be classified into class I led FDA to conduct a new review of the literature to ascertain whether it supported the proposed classification of each device or that classification urged by the comments. FDA considered the following five factors during its review of comments requesting that FDA classify certain clinical chemistry and clinical toxicology devices into class I rather than class II and its evaluation of literature relevant to these comments: (1) Whether the device test system has substantial or limited clinical utility (i.e., the extent to which an erroneous device test would have an effect on a physician's diagnosis); (2) whether class I controls, along with the establishment of a calibrator standard, would or would not be sufficient to assure the safe and effective performance of the device; (3) whether, based on the device's performance, including its accuracy, precision, sensitivity, and specificity, class I controls are adequate to assure the safe and effective performance of the device (or whether the device presents risks to health that need to be controlled by a performance standard or for which a performance standard is needed to assure the safe and effective performance of the device); (4) the absence of or presence of recalls of the device in FDA's recall-health hazard evaluation program; and (5) the absence of or frequency of reported problems with the device.

Although many comments identified specific devices, most comments were general in nature. FDA is responding below to the general comments in paragraphs 1 through 7. In paragraphs 8 through 25, FDA is responding to specific comments on certain devices and is providing reasons for changing or not changing the proposed classifications of the devices. When a comment applies to more than one device, the agency is summarizing the comment, listing the devices involved, then providing a response.

1. Several comments disputed FDA's proposals to place certain devices into class II and suggested instead that the devices be classified into class I, because medical practitioners use more than the results of a single in vitro test to evaluate a patient's condition.

FDA agrees that the results of one in vitro test usually are not the only factor used in determining the condition of a patient. However, FDA disagrees that this fact alone supports classifying all clinical chemistry and clinical toxicology devices into class I. In vitro diagnostic devices are intended for a wide variety of uses, such as to detect clinically inapparent disease, to either confirm or rule out diagnostic hypotheses, or to monitor the course of disease. If misleading or incorrect results are obtained from an in vitro test, the patient may be placed at risk.

Accordingly, FDA must consider in vitro devices individually to identify those that may be classified into class I because the tests performed using the devices are not the sole or the primary determinant of clinical diagnoses.

2. Comments requested that many devices that FDA proposed for classification into class II be classified into class I because (a) the devices are already subject to FDA's labeling requirements governing in vitro diagnostic products for human use (21 CFR 809.10) and the general controls of class I, and (b) the advisory Panel and FDA may not have appreciated the effectiveness of the general controls of class I at the time the Panel recommended and FDA proposed that the devices be classified into class II. Comments stated that the devices should be classified into class I because the agency has not shown that in vitro diagnostic devices present unreasonable risks. Comments stated that the devices have been in clinical use for many years, standards for the devices would not help prevent failures of the devices, market factors influence the emergence of safe and effective products, technology has improved performance of the devices, and voluntary standards and controls help assure the safety and effectiveness of devices. All of these factors, it was alleged, help assure that clinical chemistry and clinical toxicology devices are safe and effective, thus obviating the need for class II controls.

FDA agrees that certain clinical chemistry and clinical toxicology devices proposed for classification into class II should instead be classified into class I. However, FDA disagrees that labeling requirements and general controls alone will provide reasonable assurance of the safety and effectiveness of all clinical chemistry and clinical toxicology devices, particularly if different models or versions of the same generic type of device provide different measurements of the same factor in the same clinical specimen.

Accordingly, FDA believes that the classification of certain clinical chemistry and clinical toxicology devices into class II, and development of mandatory performance standards for these class II devices (in addition to the labeling regulations and general controls of class I), will assure that these devices provide acceptable and comparable measurement results. In paragraphs 8 through 25 below, FDA provides its reasons for classifying clinical chemistry and clinical toxicology devices into either class I or class II.

3. Many comments stated that few complaints have been reported for clinical chemistry and clinical toxicology devices in FDA's device experience network and that, even when such complaints have occurred, a performance standard would not have prevented or resolved the complaints. The comments argued that FDA's meager complaint data do not support classifying clinical chemistry and clinical toxicology devices into class II.

FDA disagrees with the comments. Although few complaints on clinical chemistry and clinical toxicology devices have been reported in its device experience network, this information is not necessarily an accurate reflection of the actual levels of adverse experiences with devices. Moreover, device experience network and medical device reporting data are not the final determinants of device classification. Nevertheless, the evidence available to FDA obtained through the medical device reporting rule (21 CFR Part 803) is in agreement with FDA's decisions in this final rule. For certain devices, FDA believes that the establishment of performance standards is necessary to provide reasonable assurance of the safety and effectiveness of the devices.

4. Many comments stated that laboratory proficiency testing is an alternative to performance standards for identifying and eliminating unsafe or ineffective devices. The comments argued that, because of proficiency testing, classification of clinical chemistry and clinical toxicology devices into class II is unnecessary.

FDA disagrees with the comments. FDA believes that proficiency testing is done primarily to measure laboratory competence, and it frequently is not possible to determine device performance from measurement of laboratory performance.

5. Many comments stated that the references cited in the proposed rule do not document problems which adequately support classification of the devices into class II.

FDA agrees that the agency should have included more information on the scientific literature supporting its proposed classifications. In this final rule, FDA is listing, discussing, and inviting comments on key references, obtained from the agency's review of the literature (1979 through 1984), that support the agency's classification decisions.

6. Two comments requested that FDA modify the identifications of most of the clinical chemistry and clinical toxicology devices by excluding (a) any examples of analytical methods and (b) any description of specific medical conditions or diseases.

FDA agrees in part and disagrees in part with the comments. FDA agrees that it is unnecessary to include examples of analytical methods in the identifications of these devices. However, FDA believes that it should describe some of the intended uses of a device. Accordingly, in each of the final rules, FDA is removing the examples of analytical methods but is retaining a brief description of some of the intended uses of the device.

7. One comment suggested that any instrument that is not used exclusively in clinical pathology laboratories not be classified as a medical device. The comment said that devices such as atomic absorption spectrophotometers, mass spectrometers, or refractometers are seldom used in the medical laboratory.

FDA disagrees with the comment. For the reasons provided in the proposal under the heading "Products That Have Both Medical and Nonmedical Uses," FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose. FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution.

8. FDA proposed that the devices listed below be classified into class II. Comments discussed above in paragraphs 1 through 5 requested that the devices be classified into class I. (The references shown in the column on the right are identified at the end of the preamble.)

Section	Device	Reference Nos.
862.1030	Alanine amino transferase (ALT/SGPT) test system	1
862.1040	Aldolase test system	2 and 3

Section	Device	Reference Nos.
862.1180	Chymotrypsin test system	4
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system	5 and 6
862.1380	Hydroxybutyric dehydrogenase test system	7
862.1420	Isocitric dehydrogenase test system	8
862.1460	Leucine aminopeptidase test system	9
862.1465	Lipase test system	10 through 12
862.1490	Lysozyme (muramidase) test system	13
862.1500	Malic dehydrogenase test system	14
862.1520	5'-Nucleotidase test system	15 and 16
862.1535	Ornithine carbamyl transferase test system	17
862.1565	6-Phosphogluconate dehydrogenase test system	18
862.1570	Phosphohexose isomerase test system	18
862.1650	Pyruvate kinase test system	19 and 20
862.1670	Sorbitol dehydrogenase test system	8
862.1720	Triose phosphate isomerase test system	21
862.1725	Trypsin test system	22 through 24
862.3240	Cholinesterase test system	25 through 28
862.1075	Androstenedione test system	33 and 34
862.1080	Androsterone test system	35
862.1135	C-peptides of proinsulin test system	36 and 37
862.1185	Compound S (11-deoxycortisol) test system	38
862.1195	Corticoids test system	39
862.1200	Corticosterone test system	
862.1245	Dehydroepiandrosterone (free and sulfate) test system	40 through 43
862.1250	Desoxycorticosterone test system	44
862.1260	Estradiol test system	45 and 46
862.1265	Estriol test system	45 and 46
862.1270	Estrogens (total, in pregnancy) test system	45 and 46
862.1275	Estrogens (total, nonpregnancy) test system	45 and 46
862.1280	Estrone test system	45 and 46
862.1300	Follicle-Stimulating hormone test system	47
862.1325	Gastrin test system	48
862.1335	Glucagon test system	49 through 51
862.1370	Human growth hormone test system	52
862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system	39
862.1395	17-Hydroxyprogesterone test system	34
862.1405	Immunoreactive insulin test system	53 and 54
862.1430	17-Ketosteroids test system	39, 42, and 55
862.1485	Luteinizing hormone test system	56 and 57
862.1605	Pregnanediol test system	
862.1610	Pregnanetriol test system	44, 58, and 59
862.1615	Pregnenolone test system	
862.1620	Progesterone test system	60 and 61
862.1625	Prolactin (lactogen) test system	62 and 63

FDA agrees with the comments. Based upon the comments and the scientific literature cited above reviewed to assist the agency in evaluating the comments, FDA concludes that the tests performed using the devices listed above are not the sole or the primary determinant of clinical diagnoses. The results obtained with the devices listed above are always considered in the context of other laboratory results and a patient's condition before a physician makes a final diagnosis or determination.

For some of the devices listed above, performance problems have been identified. These devices are nevertheless being classified into class I because their performance deviations are attributable to the device calibrator. Calibrators are marketed separately from the device as part of the device, or as part of a device kit. In any case, FDA is classifying calibrators used with clinical chemistry devices as class II devices, even if the calibrator is built into the device, or is part of a device kit, that is classified into class I. A calibrator has a reference value assigned to it which serves as the basis upon which patient tests results are derived. Because of the central role that a calibrator plays in the measurement process and the critical effects calibrators have on the accuracy of test results, elsewhere in this rule FDA is classifying calibrators (§§ 862.1150 and 862.3200) into class II. (FDA's response in paragraph 11 discusses further why calibrators are placed in class II.)

Because the tests performed using the devices listed above are not the sole or primary determinant of clinical diagnoses, and any risks to health from poor performance of the calibrator that is used with certain of the devices listed above will be controlled by classifying calibrators into class II, FDA no longer believes that performance standards are necessary for these devices. FDA now believes that the general controls of class I alone are sufficient to provide reasonable assurance of their safety and effectiveness. Accordingly, in the final rule FDA is placing the devices listed above in class I instead of class II as proposed.

9. FDA proposed that the devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons provided above in paragraphs 1 through 5.

Section	Device	Reference Nos.
862.1020	Acid phosphatase (total or prostatic) test system	29
862.1050	Alkaline phosphatase or isoenzymes test system	30
862.1070	Amylase test system	30
862.1100	Aspartate aminotransferase (AST/SGOT)	30 and 31
862.1215	Creatine phosphokinase/creatine kinase or isoenzymes system	30
862.1315	Galactose-1-phosphate uridyl transferase test system	32
862.1440	Lactate dehydrogenase test system	30
862.1445	Lactate dehydrogenase isoenzymes test system	29

FDA disagrees with the comments. The results of these devices, which are used to measure the activity of enzymes, have significant clinical utility. These tests are often relied upon by physicians as critical diagnostic aids (Refs. 29 through 32). Risks to health have been reported due to problems with some of these devices (Ref. 29), and recommendations have been made of ways to reduce the device-to-device variation in test results (Ref. 31). FDA concludes that performance standards are necessary to provide acceptable ranges of accuracy, precision, sensitivity, and specificity for these devices, thereby minimizing the possibility that the devices may generate inaccurate diagnostic information. Performance standards, therefore, are necessary to provide reasonable assurance of the safety and effectiveness of the devices. Accordingly, FDA is classifying the devices listed above into class II as proposed.

10. FDA proposed that the devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons provided in paragraph 1 through 5.

Section	*Device*	*Reference Nos.*
862.1025	Adrenocorticotropic hormone (ACTH) test system	64 and 65
862.1045	Aldosterone test system	64 through 66
862.1085	Angiotensins I and renin test system	64, 65, and 67
862.1140	Calcitonin test system	68 through 70
862.1205	Cortisol (hydrocortisone and hydroxycorticosterone) test system	44, 73, and 74
862.1545	Parathyroid hormone test system	29, 64, and 65
862.1585	Human placental lactogen test system	75
862.1685	Thyroxine-binding globulin test system	64 and 65
862.1690	Thyroid-stimulating hormone test system	64 and 65
862.1695	Free thyroxine test system	30, 64, and 65
862.1700	Total thyroxine test system	30
862.1710	Total triiodothyronine test system	30, 64, and 65
862.1715	Triiodothyronine uptake test system	30, 64, and 65

FDA disagrees with the comments. The agency believes that physicians frequently rely heavily on these tests, and that measurements of hormones obtained from use of these devices have significant clinical utility (Refs. 64 and 65). The scientific literature contains evidence that some of these devices present continuing performance problems, including problems with the devices' precision, sensitivity, or specificity (Refs. 29, 30, 44, 66 to 70, and 73 through 75). Because these performance deficiencies may lead to an erroneous diagnosis and thereby place patients at risk, these devices are being placed in class II. FDA also believes that performance standards are necessary for the devices above to provide reasonable assurance of their safety and effectiveness. Accordingly, FDA is classifying the devices listed above into class II as proposed.

11. FDA proposed that the two devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons discussed above in paragraphs 1 through 5. Further, comments argued that calibrators may be integral components of diagnostic devices and that they should be classified with the appropriate test system, not as separate devices.

Section	*Device*
862.1150	Calibrator.
862.3200	Clinical toxicology calibrator.

FDA disagrees with the comments. Many clinical chemistry and clinical toxicology devices are intended to be used with a calibrator. The calibrator for a device may be manufactured and distributed separately from the device with which it is intended to be used, manufactured and distributed as one of several device components, such as in a kit of reagents, or built-in as an integral part of the device. FDA believes that the calibrator's performance has critical effects on the accuracy of any test result, regardless of the classification of the device with which it is used. For example, even when a calibrator is built into a device classified into class I, the performance of the calibrator has critical effects on the accuracy of the test. FDA believes that performance standards are necessary for all calibrators for clinical chemistry and clinical toxicology devices (§§ 862.1150 and 862.3200) to control the concentration, stability, uniformity, and overall reliability of the devices. The agency believes that establishment of performance standards for calibrators would provide reasonable assurance of the safety and effectiveness of the devices with which they are used and that sufficient information exists to establish such standards. Accordingly, FDA is adopting the proposed regulations classifying the devices above without change. To clarify its classification regulations, FDA also is adding in Subpart A new § 862.2 *Regulation of calibrators.*

12. FDA proposed that the devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons provided in paragraphs 1 through 5.

Section	Device	Reference Nos.
862.1060	Delta-aminolevulinic acid test system	76 and 77
862.1065	Ammonia test system	78 and 79
862.1095	Ascorbic acid test system	80
862.1115	Urinary bilirubin and its conjugates (non-quantitative) test system	
862.1130	Blood volume test system	81 through 84
862.1165	Catecholamines (total) test system	85 through 91
862.1175	Cholesterol (total) test system	92 and 93
862.1190	Copper test system	94 and 95
862.1210	Creatine test system	96
862.1240	Cystine test system	97
862.1255	2,3-Diphosphoglyceric acid test system	
862.1285	Etiocholanolone test system	98 and 99
862.1290	Fatty acids test system	100
862.1305	Formiminoglutamic acid (FIGLU) test system	32, 101, and 102
862.1310	Galactose test system	103
862.1320	Gastric acidity test system	
862.1330	Globulin test system	104
862.1365	Glutathione test system	105
862.1375	Histidine test system	64 and 106
862.1390	5-Hydroxyindole acetic acid/serotonin test system	107
862.1400	Hydroxyproline test system	108 through 110
862.1410	Iron (non-heme) test system	108 and 109
862.1415	Iron-binding capacity test system	111 through 113
862.1450	Lactic acid test system	

Section	Device	Reference Nos.
862.1470	LKipid (total) test system	
862.1475	Lipoprotein test system	115 and 116
862.1495	Magnesium test system	117 and 118
862.1510	Urinary nitrites (nonquantitative) test system	119
862.1515	Nitrogen (amino-nitrogen) test system	
862.1530	Plasma oncometry test system	120
862.1540	Osmolality test system	120 and 121
862.1550	Urinary pH (nonquantitative) test system	80
862.1560	Urinary phenylketones (nonquantitative test system	
862.1575	Phospholipid test system	
862.1580	Phosphorus (inorganic) test system	122
862.1590	Porphobilinogen test system	123
862.1595	Porphyrins test system	124
862.1630	Protein (fractionation) test system	
862.1640	Protein-bound iodine test system	
862.1645	Urinary protein or albumin (nonquantitative) test system	80 and 125 through 127
862.1655	Pyruvic acid test system	
862.1705	Triglyceride test system	88 through 90, 128, and 129
862.1730	Free tyrosine test system	130
862.1775	Uric acid test system	131
862.1780	Urinary calculi (stone) test system	96 and 132
862.1785	Urinary urobilinogen (nonquantitative) test system	80 and 133
862.1790	Uroporphyrin test system	133 and 134
862.1795	Vanilmandelic acid test system	
862.1805	Vitamin A test system	136 through 138
862.1815	Vitamine E test system	
862.1820	Xylose test system	139 and 140
862.3110	Antimony test system	
862.3120	Arsenic test system	
862.3220	Carbon monoxide test system	141 and 142
862.3600	Mercury test system	143

FDA agrees with the comments. Based upon the comments and the scientific literature cited above reviewed to assist the agency in evaluating the comments, FDA concludes that the labeling regulations in 21 CFR 809.10, the general controls of class I, and establishment of a standard for the calibrator for each of these devices (as noted above) will provide reasonable assurance of the safety and effectiveness of the devices above. Some of these devices measure less diagnostically useful levels of constituents of body fluids. Others measure diagnostically significant levels of constituents of body fluids with a very high degree of reliability. In either case, the measurements provided by use of these devices may be substantiated by other means and, in some cases, the devices are used merely as an aid in the diagnosis or treatment of normally noncritical conditions. Accordingly, in the final rule FDA is classifying the devices listed above into class I rather than class II as proposed.

13. FDA proposed that the devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons provided above in paragraphs 1 through 5.

Section	Device	Reference Nos.
862.1035	Albumin test system	144 through 149
862.1110	Bilirubin (total or direct) test system.	150 through 152
862.1120	Blood gases ($P_{co}2$, P_o2), and blood $_pH$ test system.	150 through 153
862.1145	Calcium test system	150 through 154
862.1160	Bicarbonate/carbon dioxide test system.	153
862.1170	Chloride test system	150
862.1225	Creatinine test system.	155
862.1295	Folic acid test system	156 and 157
862.1340	Urinary gloucose (nonquantitative) test system.	158 through 164
862.1345	Glucose test system	150 through 162
862.1455	Lecithin-sphingomyelin ratio in amniotic fluid test system.	165 through 167
862.1555	Phenylalanine test system.	101, 130, and 168
862.1600	Potassium test system.	150
862.1635	Total protein test system.	126, 127, 148 through 148, and 169, through 171
862.1665	Sodium test system	150 and 172
862.1770	Urea nitrogen test system.	173 through 177
862.1810	Vitamin B12 test system.	178 through 185
862.3550	Lead test system	150 and 186

FDA disagrees with the comments. The agency believes that insufficient information exists to determine that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. These devices are used to measure diagnostically critical analyses as an aid in the diagnosis and treatment of seriously ill patients. The literature (Refs. 15, 101, 126, 127, 130, and 144 through 186) provides evidence of continuing risks to health resulting from deficiencies in the accuracy and precision of a number of these devices. The agency believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the devices and sufficient information is available to establish such standards. Accordingly, in this final rule FDA is classifying the devices listed above into class II as proposed.

14. FDA proposed that the two devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons discussed in paragraphs 1 through 5.

Section	Device
862.3750	Quinine test system.
862.3850	Sulfonamide test system.

FDA agrees with the comments. FDA now believes that the general controls of class I alone are sufficient to provide reasonable assurance of the safety and effectiveness of the two devices. In the scientific literature that FDA reviewed to evaluate the comments, FDA found no evidence of problems with the performance of the devices (Ref. 187). Accordingly, in the final rule FDA is classifying the devices into class I rather than class II as proposed.

15. FDA proposed that the devices listed below be classified into class II. Comments requested that the devices be classified into class I for the reasons discussed in paragraphs 1 through 5.

Section	Device
862.3040	Alcohol test system.
862.3100	Amphetamine test system.
862.3150	Barbiturate test system.
862.3170	Benzodiazepine test system.
862.3250	Cocaine and cocaine metabolite test system.
862.3270	Codeine test system.
862.3300	Digitoxin test system.
862.3320	Digoxin test system.
862.3350	Diphenylhydantoin test system.
862.3380	Ethosuximide test system.
862.3450	Gentamicin test system.
862.3520	Kanamycin test system.
862.3560	Lithium test system.
862.3580	Lysergic acid diethylamide (LSD) test system.
862.3610	Methamphetamine test system.
862.3620	Methadone test system.
862.3640	Morphine test system.
862.3650	Opiate test system.
862.3660	Phenobarbital test system.
862.3670	Phenothiazine test system.
862.3680	Primidone test system.
862.3700	Propoxyphene test system.
862.3830	Salicylate test system.
862.3870	Cannabinoid test system.
862.3900	Tobramycin test system.

FDA disagrees with the comments. These devices, which include devices intended both for the measurement of therapeutic drugs and of drugs of abuse, are of major importance in the management of illnesses and acute medical conditions. With many of these drugs, the difference is narrow between a therapeutic and a toxic blood level. Assays of a high degree of accuracy are required to provide reasonable assurance of the safety and

effectiveness of these devices used for drug assays. Similarly, highly sensitive and dependable assays are essential for the prompt treatment of persons exposed to drugs of abuse (Refs. 150, 186, and 188 through 190). Literature reviewed to evaluate the comments reveals that risks to health resulting from lack of accuracy and precision need to be resolved, and reference methods and reliable reference materials must be established for therapeutic drug assays (Ref. 188). Therefore, the agency believes that performance standards are necessary to ensure acceptable ranges of accuracy, precision, sensitivity, and specificity, thereby minimizing the possibility that the devices may generate inaccurate diagnostic information, and to provide reasonable assurance of safety and effectiveness of the devices. Accordingly, in the final rule FDA is classifying the devices listed above into class II as proposed.

16. Section 862.1230; Cyclic AMP test system.

FDA proposed that the cyclic AMP and the cyclic GMP test system be classified into class II. A comment stated that the devices are not commercially marketed at this time and are intended only for research purposes.

FDA agrees that the cyclic GMP test system has been marketed only for research purposes and is not being marketed commercially. However, the cyclic AMP test system is being marketed, as discussed below. Therefore, in the final rule FDA is changing the name of the device and its identification to remove the cyclic GMP test system.

FDA believes that evidence of safety and effectiveness has been established (as defined in 21 CFR 860.7) for the cyclic AMP test system intended for use in measuring cyclic AMP in urine or plasma in response to administering parathyrin for diagnosing pseudohypoparathyroidism (Refs. 191 through 193) and that the device is being commercially marketed for this purpose. FDA believes that performance standards are necessary for this device to provide acceptable ranges of accuracy, precision, sensitivity, and specificity, thereby minimizing the possibility that the device may generate inaccurate diagnostic information, and to provide reasonable assurance of safety and effectiveness of the device. Accordingly, in the final rule, FDA is changing the name of the device and its identification and is classifying the cyclic AMP test system into class II as proposed.

17. Section 862.1435; Ketones (nonquantitative) test system: proposed class II.

Comments requested that the device be classified into class I rather than class II based on the arguments summarized above in paragraphs 1 through 5 and on the argument that general controls are adequate safeguards for nonquantitative assays of random urine samples. Comments also requested that the identification of the device be broadened to include both urine and serum nonquantitative systems, citing literature references and established current clinical use.

FDA agrees with the comments. Because of these comments and evidence in the scientific literature (Ref. 80), the agency now believes that the general controls of class I and the labeling requirements of 21 CFR 809.10 are sufficient to provide reasonable assurance of the safety and effectiveness of this device. The agency further believes that it is well known that the qualitative measurement in vitro of ketones in serum improves management of ketotic conditions. In addition, FDA is clarifying the name of the generic type of device and, for the reasons above and reasons provided in the response in paragraph 12, classifying the device into class I. Accordingly, FDA is classifying the device into class I rather than class II as proposed and is changing the identification of the device to include urine and serum nonquantitative test systems.

18. Section 862.1505; Mucopolysaccharides (nonquantitative) test system; proposed class II.

Comments requested that the device be classified into class I rather than class II based on the arguments above in paragraphs 1 through 5. Two of the comments argued that this test is only a screening procedure. One comment also requested clarification of the identification of the device concerning its use with boldy fluids other than urine.

FDA agrees with the comments. Based upon these comments and the scientific literature reviewed to evaluate the comments, the agency now believes that the general controls of class I and the labeling requirements of 21 CFR 809.10 are sufficient to provide reasonable assurance of the safety and effectiveness of this device (Ref. 194). The agency also believes that these test systems are intended for use only to assay mucopolysaccharides in urine and not to assay other body fluids, such as serum or plasma. For the reasons above and the reasons provided in the response in paragraph 12, in the final rule FDA is classifying the device into class I rather than class II and is changing the identification of the device to delete mention of its use with serum or plasma.

19. Section 862.1675; Blood specimen collection device; proposed class II.

Comments requested that the device be classified into class I rather than class II based on the arguments above in paragraphs 1 through 5.

FDA disagrees with the comments. Risks to health that result from various kinds of contamination involving blood specimen collection devices continue to be reported in current literature (Refs. 150 and 195 through 197). Considering the critical effects of analytical interference on the results of virtually all blood assays, FDA believes that a performance standard is necessary for the blood specimen collection device to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, in the final rule FDA is classifying the device into class II as proposed.

20. Section 862.1680; Testosterone test system.

FDA proposed that the testosterone and dihydrotestosterone test system be classified into class II. Comments requested that the device be classified into class I rather than class II based on the arguments above in paragraphs 1 through 5. Also, a comment stated that only one manufacturer distributes a device intended to measure dihydrotestosterone and that this manufacturer has never made clinical claims for the product, because it is intended for research purposes. The comment requested that the dihydrotestosterone test system not be classified as an in vitro diagnostic device, because the device has not been commercially marketed.

FDA agrees with the comments. For the reasons provided in paragraph 8. FDA is classifying the device into class I rather than class II. The agency agrees that the dihydrotestosterone test system has been distributed only for research purposes (Refs. 24, 198, and 200). Accordingly, in the final rule FDA is adopting the proposed regulation, with a change in the name of the generic type of device and its identification to remove reference to the dihydrotestosterone test system, and is classifying the device into class I rather than class II as proposed.

21. Section 862.2050; General purpose laboratory equipment; proposed class I.

A comment requested that the identification of general purpose laboratory equipment be modified to be consistent with the definition of general

purpose articles in the registration and listing regulations in 21 CFR 807.65(c). In addition, after the close of the comment period on this proposed regulation, FDA received a petition (83P-0162/CP) requesting FDA to withdraw proposed § 862.2050 because the petitioner claimed that laboratory equipment is not a device within the meaning of section 201(h) of the act. FDA denied the petition, because laboratory equipment intended for a medical use is a device, as discussed below.

FDA believes that its proposed rule classifying this generic type of device was not inconsistent with 21 CFR 807.65(c). However, to alleviate any concerns, in the final rule FDA is changing the name of the device from "general purpose laboratory equipment" to "general purpose laboratory equipment labeled or promoted for a specific medical use." FDA also is clarifying the identification of the device. FDA intended to classify as a device only the general purpose laboratory equipment that is intended to prepare or examine specimens from the human body and that is labeled or promoted from a specific medical use; and exclude from the device identification any general purpose laboratory equipment that is not labeled or promoted for a specific medical use. FDA explained its policy on regulation of multi-purpose products in the preamble to the proposed rule (47 FR 4802 at 4804) under "Products that Have Both Medical and Nonmedical Uses." Accordingly, FDA is adopting the proposed regulation with clarifying changes in the name of the device and its identification.

22. Section 862.2100; Calculator/data processing module for clinical use; proposed class I.

A comment requested that the identification of the generic type of device be clarified and expanded to include certain equipment used in conjunction with the diverse computer systems in current use.

FDA agrees with the comment. The agency is revising the identification of the device to include the devices employed in current data-handling technologies. Accordingly, FDA is adopting the proposed regulation with a clarifying change in the identification of the device.

23. Section 862.2300; Colorimeter, photometer, or spectrophotometer for clinical use; proposed class I.

A comment requested that the identification of the generic type of device be clarified and expanded to be more inclusive.

FDA agrees with the comment. The agency is broadening the identification of the device to include the various instruments used for the diverse optical techniques in current use. Accordingly, FDA is adopting the proposed regulation with a clarifying change in the identification of the device.

24. Section 862.2230; Chromatographic separation material for clinical use; proposed class I.

One comment expressed concern that FDA's different classification of chromatographic separation materials and the devices that incorporate the materials as components. The comment stated that it is confusing and inconsistent for FDA to classify several diagnostic devices utilizing chromatographic separation materials into class II, while the chromatographic separation materials themselves are proposed for class I.

FDA disagrees with the comment. FDA's classification of a diagnostic test system is based on the degree of control necessary to provide reasonable assurance of the safety and effectiveness of the generic type of device (i.e., the complete device). To achieve this outcome, FDA must at times classify a device and a device component differently, particularly when the component is separately available for purchase. Chromatographic materials are commercially available independent of the devices with which they are intended for use and are adequately regulated with class I controls. Therefore, it is reasonable to regulate chromatographic materials in class I instead of increasing the applicable regulatory control to class II merely to obtain consistency with the classification of a device requiring a greater degree of regulatory control. Accordingly, the proposed regulation concerning chromatographic separation material for clinical use is being adopted as proposed.

25. Section 862.1155; Human chorionic gonadotropin (HCG) test system.

FDA proposed that the human chorionic gonadotropin (HCG) test system for use in the early detection of pregnancy be classified into class II. Comments requested that the device be classified into class I rather than class II.

FDA disagrees with the comments. The agency believes that the human chorionic gonadotropin test system has significant clinical utility. FDA notes that the scientific literature contains evidence that the device continues to present problems, including variations in analytical sensitivity and specificity (Refs. 71 and 72), that should be addressed by a performance standard to provide reasonable assurance of the safety and effectiveness of the device.

In its proposed regulations for this device (47 FR 4808), FDA stated that human chorionic gonadotropin HCG test systems intended for uses other than the early detection of pregnancy, such as intended for use in the diagnosis and management of treatment of trophoblastic tumors and carcinomas of the stomach, liver, pancreas, and breast, were investigational devices not in commercial distribution when the amendments were enacted. FDA stated in the proposal that these devices intended for uses other than the early detection of pregnancy are already classified into class III (premarket approval) by section 513(f) of the act; and that under the statute these devices intended for these other uses are subject to premarket approval without the 30-month grace period applicable to class III devices of the type that were in commercial distribution on the enactment date of the amendments (see §§ 513(f)(1), 515(a), and 501(f)(1)(B) of the act (21 U.S.C. 360c(f)(1), 360e(a) and 351(f)(1)(B))).

If FDA knows that a device being commercially distributed may be a "new" device as described above because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. The classification regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

FDA believes that human chorionic gonadotropin (HCG) test systems may be commercially distributed while intended for new uses, i.e., uses for diagnosis and management of treatment of trophoblastic tumors and certain carcinomas. FDA is codifying the statutory classification of the new device into class III for such new uses (§ 862.1155(b)), as specified in § 862.3(b). FDA's belief that the device may be commercially distributed for these new uses is based on its review of an article in "Obstetrics and Gynecology" (Ref. 201). Hussa reviews the findings of numerous investigators regarding the clinical utility of HCG. The review indicates that the development of highly sensitive and specific radioimmunoassays for HCG has expanded the utility of HCG measurements from pregnancy testing to applications in a variety of clinical conditions. HCG determinations are increasingly being used as diagnostic aids for conditions such as: Molar

pregnancy and trophoblastic disease, gestational choriocarcinoma (as a follow-up), hydatidiform mole (as a postevacuation follow-up), ectopic pregnancy, threatened abortion, and nonseminomatous germ cell testicular tumors (as a staging and follow-up). Accordingly, in this final rule FDA is adopting the regulation for human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy as proposed with clarifying changes and codifying the statutory classification of the device into class III if intended for any uses other than early detection of pregnancy, such as in the diagnosis and management of certain tumors and carcinomas.

26. FDA has made clarifying and conforming changes in the identifications of test systems used to detect abusable drugs in body fluids, e.g., blood, serum, and urine (§§ 862.3100, 862.3150, 862.3170, 862.3250, 862.3270, 862.3580, 862.3610, 862.3620, 862.3630, 862.3640, 862.3650, 862.3660, 862.3670, 862.3700, 862.3870, and 862.3910.

G. Exemptions for Class I Devices

FDA received no comments regarding exemptions for clinical chemistry and clinical toxicology devices. FDA proposed that manufacturers of one class I clinical chemistry and clinical toxicology device, general purpose laboratory equipment (§ 862.2050), and of manufacturers of certain components of the thin-layer chromatography system for clinical use (§ 862.2270), be exempt from the current good manufacturing practice (CGMP) regulations with the exception of the requirements specified in 21 CFR 820.180 and 820.198 relating to records and complaint files. In this final rule, FDA is granting the exemptions that were proposed.

As stated in the proposed rule, the agency has determined that exemption of manufacturers of any device from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and follow-up. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate. Also for the reasons given in the proposed regulations, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device CGMP regulations. These petitions may be submitted in accordance with the provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). The agency announced the availability of these guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

FDA proposed to grant an exemption from the requirement of premarket notification for one clinical chemistry and clinical toxicology device, general purpose laboratory equipment (§ 862.2050). In the final rule, FDA is granting the device, with its modified description, an exemption from the requirement of premarket notification as proposed.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification for certain class I clinical chemistry and clinical toxicology devices. FDA is also explaining in that proposed rule the agency's recently developed policy on granting such exemptions from premarket notification.

H. Reclassification of Devices

Postamendments devices that are not substantially equivalent to devices marketed before the amendments are classified by statute into class III under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). In response to petitions received by FDA under section 513(f)(2) of the act and Part 860 of the regulations, FDA may reclassify a new device into class I or class II.

FDA received a number of such petitions requesting reclassification into class I or class II of certain clinical chemistry and clinical toxicology devices. FDA then published in the **Federal Register** the recommendations of the Panel on these petitions, to provide a period for public comment. FDA is presenting in the table below a summary of its actions on the petitions and is providing, after the table, a summary of any comments received and FDA's responses to the comments. By order in the form of a letter to each petitioner, FDA reclassified each of these devices. Accordingly, in this final rule FDA is announcing its reclassifications under 21 CFR 860.134 and codifying its reclassifications of the devices listed below.

FDA's order and regulation codifying reclassification of a device applies to any device which is substantially equivalent to the reclassified device. FDA determines substantial equivalence of new devices by reviewing premarket notification submissions under section 510(k) of the act and Subpart E of 21 CFR Part 807.

Section No.	Petition number/date petition received by FDA	Generic type of device	Class recommended by Section	FEDERAL REGISTER cite for notice/public comments on notice	Date of FDA's order reclassifying device/FDA's classification of device
862.1090	77N-0394, Oct. 3, 1977	Angiotensin converting enzyme test system.	II	March 31, 1978; 43 FR 13631; no comments were received.	May 23, 1978; Class II.
862.1177	78P-0058, Feb. 14, 1978	Cholylglycine test system	II	June 6, 1978; 43 FR 24600; no comments were received.	July 26, 1978; Class II.
862.1187	78N-0185, Feb. 15, 1978	Conjugated sulfolithocholic acid test system.	II	June 30, 1978; 43 FR 28557; no comments were received.	Aug. 3 1978; Class II.
862.1315	78P-0003, Dec. 9, 1977	Galactose-1-phosphate uridyl transferase test system.	II	June 6, 1978; 43 FR 24605; no comments were received.	July 26, 1978; Class II.
862.1377	80P-0510, Oct. 9, 1980	Urinary homocystine (nonquantitative) test system.	II	July 7, 1981; 46 FR 35189; no comments were received.	Aug. 25, 1981; Class II.
862.1509	80P-0511, Oct. 9, 1980	Urinary methylmalonic acid (nonquantitative) test system.	II	July 7, 1981; 46 FR 35191; no comments were received.	Aug. 25, 1981; Class II.
862.1542	84P-0212, April 19, 1983	Oxalate test system	I	July 3, 1984; 49 FR 27371; no comments were received.	Sept. 7, 1974; Class I.
862.3030	79P-0317, May 7, 1979	Acetaminophen test system	II	April 22, 1980; 45 FR 27016; no comments were received.	June 9, 1980; Class II.
862.3035	77P-0338, Aug. 16, 1977	Amikacin test system	II	Jan. 13, 1978; 43 FR 1995; one comment was received—see paragraph 1 below.	March 2, 1978; Class II.

Section No.	Petition number/date petition received by FDA	Generic type of device	Class recommended by Section	FEDERAL REGISTER cite for notice/public comments on notice	Date of FDA's order reclassifying device/FDA's classification of device
862.3035	77P-0342, Aug. 8, 1977	Amikacin test system	II	Feb. 7, 1978; 43 FR 5068; one comment was received—see paragraph 2 below.	March 30, 1978; Class II.
862.3280	78P-0268, July 10, 1978	Clinical toxicology control material	I	March 13, 1979; 44 FR 14639; no comments were received.	March 31, 1982; Class I.
862.3250	77N-0431, Aug. 20, 1976	Cocaine and cocaine metabolite test system.	II	Feb. 7, 1978; 43 FR 5070; no comments were received.	March 29, 1978; Class II.
862.3450	77P-0287, June 23, 1977	Gentamicin test system	II	Jan. 31, 1978; 43 FR 4116; one comment was received—see paragraph 3 below.	March 13, 1978; Class II.
862.3555	78P-0341, Aug. 4, 1977	Lidocaine test system	II	Feb. 3, 1978; 43 FR 4682; no comments were received.	March 20, 1978; Class II.
862.3630	77P-0052, Aug. 24, 1976	Methaqualone test system	II	Feb. 24, 1978; 43 FR 7711; no comments were received.	April 7, 1978; Class II.
862.3645	82P-0263, May 6, 1982	Neuroleptic drugs radioreceptor assay test system.	II	Aug. 16, 1983; 48 FR 37080; no comments were received.	Dec. 23, 1983; Class II.
862.3880	77P-0340, Aug. 4, 1977	Theophylline test system	II	Jan. 13, 1978; 43 FR 1996; no comments were received.	March 2, 1978; Class II.
862.3910	79P-0091, March 21, 1979	Tricyclic anti-depressant drugs test system	II	Nov. 30, 1979; 44 FR 69011; no comments were received.	Jan. 26, 1980; Class II.

Section No.	Petition number/date petition received by	Generic type of device	Class recommended by Section	FEDERAL REGISTER cite for notice/public comments on notice	Date of FDA's order reclassifying device/FDA's classification of device
862.3950	80P-0142, Sept. 10, 1979	Vancomycin test system	II	April 29, 1980; 45 FR 28497	July 12, 1980; Class II.

1. FDA received a comment on the recommendation on the Amikacin test system (§ 862.3035, petition 77P-0338). The comment suggested that compliance with current good manufacturing practice (CGMP) regulations and adequate labeling would be sufficient to ensure the safe and effective use of "Amikacin Serum Assay." The comment indicated that the device should be classified in class I.

FDA disagrees with the comment. FDA believes that compliance with CGMP regulations and use of adequate labeling are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that establishment of a performance standard for the device is necessary to provide acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimize the possibility that the device would provide inaccurate diagnostic information. FDA believes that a performance standard is needed to provide reasonable assurance of the safety and effectiveness of the device and that sufficient information is available to develop such a standard.

2. FDA received a second comment on the recommendation on the Amikacin test system (§ 862.3035, petition 77P-0342) concerning the content of a future performance standard. The comment recommended that parameters such as antibody content, antibody quality, moisture content, pH, and other appropriate characteristics be included in the standard.

FDA agrees with the comment. FDA believes that the specific characteristics suggested by the comment should be addressed in any performance standard.

3. FDA received one comment on the recommendation on the Gentamicin test system (§ 862.3450, petition 77P-0287). The comment suggested that the following attributes be addressed in the standard: Gentamicin content, antibody content, antibody quality moisture content, pH, and other appropriate chacteristics.

FDA agrees with the comment. FDA agrees that the suggested attributes should be addressed in any performance standard.

I. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	March 9, 1979; 44 FR 13284-13434 (proposals); February 5, 1980; 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Services Panel.	February 2, 1982; 47 FR 4802-4929 (proposals); May 1, 1987 (final regulations and proposals).
Hematology and Pathology Devices Panel.	September 11, 1979; 44 FR 52950-53063 (proposals); September 12, 1980; 45 FR 60576-60651 (final regulations).
General Hospital and Personal Use Devices Panel.	August 24, 1979; 4 FR 49844-49954 (proposals); October 21, 1980; 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Devices Panel.	January 23, 1981; 46 FR 7562-7641 (proposals); November 23, 1983; 48 FR 52012-53029 (final regulations).
Immunology Devices Panel.	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Microbiology Devices Panel.	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel.	April 3, 1979; 44 FR 19894-19971 (proposals); February 26, 1980; 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel.	January 29, 1982; 47 FR 4406-4451 (proposals).
Ear, Nose, and Throat Devices Panel.	January 22, 1982; 47 FR 3280-3325 (proposals); November 6, 1986; 51 FR 40378 (final regulations).
Dental Devices Panel	December 30, 1980; 45 FR 85962-86168 (proposals).
Anesthesiology and Respiratory Therapy Devices Panel.	November 2, 1979; 44 FR 63292-63426 (proposals); July 16, 1982; 47 FR 31130-31150 (final regulations).
Neurological Devices Panel.	November 23, 1978; 43 FR 54640-55732 (proposals); September 4, 1979; 44 FR 51726-51778 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices).	August 28, 1979; 44 FR 50458-50537 (proposals); November 23, 1983; 48 FR 53032-53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices).	July 2, 1982; 47 FR 29052-29140 (proposals).
General and Plastic Surgery Devices Panel.	January 19, 1982; 47 FR 2810-2853 (proposals).

J. References

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

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K. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

L. Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has detemined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section (b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, remain subject only to such controls either in their entirety or with certain exemptions. Those devices classified into class II will remain subject only to the general controls provisions of the act unless and until applicable performance standards are established. In sum, the device classification rules do not have a significant impact on a substantial number of small entities, are not major rules, and do not significantly change the regulatory status of the devices subject to classification.

Interested persons may, on or before June 30, 1987, submit to the Dockets Management Branch (address above) written comments regarding the regulations for those devices whose classifications in the final rule are different from their proposed classifications. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 862

Clinical chemistry and clincial toxicology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21

of the Code of Federal Regulations is amended by adding new Part 862, to read as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Clinical Chemistry Test Systems

Subpart C—Clinical Laboratory Instruments

862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.
862.2100 Calculator/data processing module for clinical use.
862.2140 Centrifugal chemistry analyzer for clinical use.
862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.
862.2160 Discrete photometric chemistry analyzer for clinical use.
862.2170 Microchemistry analyzer for clinical use.
862.2230 Chromatographic separation material for clinical use.
862.2250 Gas liquid chromatography system for clinical use
862.2260 High-pressure liquid chromatography system for clinical use.
862.2270 Thin-layer chromatography system for clinical use.
862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.
862.2310 Clinical sample concentrator.
862.2320 Beta- or gamma-counter for clinical use.
862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
862.2485 Electophoresis apparatus for clinical use.
862.2500 Enzyme analyzer for clinical use.
862.2540 Flame emission photometer for clinical use.
862.2560 Fluorometer for clinical use.
862.2680 Microtitrator for clinical use.
862.2700 Nephelometer for clinical use.
862.2720 Plasma oncometer for clinical use.
862.2730 Osmometer for clinical use.
862.2750 Pipetting and diluting system for clinical use.
862.2800 Refractometer for clinical use.
862.2850 Atomic absorption spectrophotometer for clinical use.
862.2860 Mass spectrometer for clinical use.
862.2900 Automated urinalysis system.
862.2920 Plasma viscometer for clinical use.

Subpart D—Clinical Toxicology Test Systems

862.3030 Acetaminophen test system.
862.3035 Amikacin test system.
862.3040 Alcohol test system.
862.3050 Breath-alcohol test system.
862.3100 Amphetamine test system.
862.3110 Antimony test system.
862.3120 Arsenic test system.
862.3150 Barbiturate test system.
862.3170 Benzodiazepine test system.
862.3200 Clinical toxicology calibrator.
862.3220 Carbon monoxide test system.
862.3240 Cholinesterase test system.
862.3250 Cocaine and cocaine metabolite test system.
862.3270 Codeine test system.
862.3280 Clinical toxicology control material.
862.3300 Digitoxin test system.
862.3320 Digoxin test system.
862.3350 Diphenylhydantoin test system.
862.3380 Ethosuximide test system.
862.3450 Gentamicin test system.
862.3520 Kanamycin test system.
862.3550 Lead test system.
862.3555 Lidocaine test system.
862.3560 Lithium test system.
862.3580 Lysergic acid diethylamide (LSD) test system.
862.3600 Mercury test system.
862.3610 Methamphetamine test system.
862.3620 Methadone test system.
862.3630 Methaqualone test system.
862.3640 Morphine test system.
862.3645 Neuroleptic drugs radioreceptor assay test system.
862.3650 Opiate test system.
862.3660 Phenobarbital test system.
862.3670 Phenothiazine test system.
862.3680 Primidone test system.
862.3700 Propoxyphene test system.
862.3750 Quinine test system.
862.3830 Salicylate test system.
862.3850 Sulfonamide test system.
862.3870 Cannabinoid test system.
862.3880 Theophylline test system.
862.3900 Tobramycin test system.
862.3910 Tricyclic antidepressant drugs test system.
862.3950 Vancomycin test system.

Authority. Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference value assigned to it which serves as the basis by which test results of patients are derived or calculated. The calibrator for a device may be (a) manufactured and distributed separately from the device with which it is intended to be used, (b) manufactured and distributed as one of several device components, such as in a kit of reagents, or (c) built-in as an integral part of the device. Because of the central role that a calibrator plays in the measurement process and the critical effect calibrators have on accuracy of test results, elsewhere in this part, all three of these types of calibrators (§§ 862.1150 and 862.3200) (21 CFR 862.1150 and 862.3200) are classified into class II, notwithstanding the classification of the device with which it is intended to be used. Thus, a device and its calibrator may have different classifications, even if the calibrator is built into the device.

§ 862.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without

any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

Subpart B—Clinical Chemistry Test Systems

§ 862.1020 Acid phosphatase (total or prostatic) test system.

(a) *Identification.* An acid phosphatase (total or prostatic) test system is a device intended to measure the activity of the acid phosphatase enzyme in plasma and serum.

(b) *Classification.* Class II.

§ 862.1025 Adrenocorticotropic hormone (ACTH) test system.

(a) *Identification.* an Adrenocorticotropic hormone (ACTH) test system is a device intended to measure adrenocorticotropic hormone in plasma and serum. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

(b) *Classification.* Class II.

§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.

(a) *Identification.* An alanine amino transferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

(b) *Classification.* Class I.

§ 862.1035 Albumin test system.

(a) *Identification.* An albumin test system is a device intended to measure the albumin concentration in serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

(b) *Classification.* Class II.

§ 862.1040 Aldolase test system.

(a) *Identification.* An aldolase test system is a device intended to measure the activity of the enzyme aldolase in serum or plasma. Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive Duchenne-type muscular dystrophy.

(b) *Classification.* Class I.

§ 862.1045 Aldosterone test system.

(a) *Identification.* An aldosterone test system is a device intended to measure the hormone aldosterone in serum and urine. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

(b) *Classification.* Class II.

§ 862.1050 Alkaline phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

§ 862.1060 Delta-aminolevulinic acid test system.

(a) *Identification.* A *delta*-aminolevulinic acid test system is a device intended to measure the level of *delta*-aminolevulinic acid (a precursor of porphyrin) in urine. *Delta*-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including *delta*-aminolevulinic acid).

(b) *Classification.* Class I.

§ 862.1065 Ammonia test system.

(a) *Identification.* An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification.* Class I.

§ 862.1070 Amylase test system.

(a) *Identification.* An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification.* Class II.

§ 862.1075 Androstenedione test system.

(a) *Identification.* An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Adrostenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(b) *Classification.* Class I.

§ 862.1080 Androsterone test system.

(a) *Identification.* An androsterone test system is a device intended to measure the hormone adrosterone in serum, plasma, and urine. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal diseases.

(b) *Classification.* Class I.

§ 862.1085 Angiotensin I and renin test system.

(a) *Identification.* An angiotensin I and renin test system is a device intended to measure the level of angiotensin I generated by renin in plasma. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.

(b) *Classification.* Class II.

§ 862.1090 Angiotensin converting enzyme (A.C.E.) test system.

(a) *Identification.* An angiotensin converting enzyme (A.C.E.) test system is a device intended to measure the activity of angiotensin converting enzyme in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as sarcoidosis, a disease characterized by the formation of nodules in the lungs, bones, and skin, and Gaucher's disease, a hereditary disorder affecting the spleen.

(b) *Classification.* Class II.

§ 862.1095 Ascorbic acid test system.

(a) *Identification.* An ascorbic acid test system is a device intended to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine. Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

(b) *Classification.* Class I.

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

(a) *Identification.* An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

(b) *Classification.* Class II.

§ 862.1110 Bilirubin (total or direct) test system.

(a) *Identification.* A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal distruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

(b) *Classification.* Class II.

§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

(a) *Identification.* A urinary bilirubin and its conjugates (nonquantitative) test system is a device intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

(b) *Classification.* Class I.

§ 862.1120 Blood gases ($P_{CO}2$, P_O2) and blood pH test system.

(a) *Identification.* A blood gases ($P_{CO}2$, P_O2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases ($P_{CO}2$, P_O2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II.

§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(b) *Classification.* Class I.

§ 862.1135 C-peptides of porinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(b) *Classification.* Class I.

§ 862.1140 Calcitonin test system.

(a) *Identification.* A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).

(b) *Classification.* Class II.

§ 862.1145 Calcium test system.

(a) *Identification.* A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

(b) *Classification.* Class II.

§ 862.1150 Calibrator.

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. (See also § 862.2 in this part.)

(b) *Classification.* Class II.

§ 862.1155 Human chorionic gonadotropin (HCG) test system.

(a) *Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy*—(1) *Identification.* A human chorionic gonadotropin (HCG) test system is a device intended for the early detection of pregnancy is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class II.

(b) *Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy*—

(1) *Identification.* A human chorionic goadotropin (HCG) test system is a device intended for any uses other than early detection of pregnancy (such as an aid in the diagnosis, prognosis, and management of treatment of persons with certain tumors or carcinomas) is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 862.3.

§ 862.1160 Bicarbonate/carbon dioxide test system.

(a) *Identification.* A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

(b) *Classification.* Class II.

§ 862.1165 Catecholamines (total) test system.

(a) *Identification.* A catecholamines (total) test system is a device intended to determine whether a group of similar compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromo-cytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

(b) *Classification.* Class I.

§ 862.1170 Chloride test system.

(a) *Identification.* A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II.

§ 862.1175 Cholesterol (total) test system.

(a) *Identification.* A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(b) *Classification.* Class I.

§ 862.1177 Cholylglycine test system.

(a) *Identification.* A cholylglycine test system is a device intended to measure the bile acid cholylglycine in serum. Measurements obtained by this device are used in the diagnosis and treatment

of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1180 Chymotrypsin test system.

(a) *Identification.* A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(b) *Classification.* Class I.

§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) *Identification.* A compound S (11-dioxycortisol) test system is a device intended to measure the level of compound S (11-dioxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(b) *Classification.* Class I.

§ 862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

(a) *Identification.* A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1190 Copper test system.

(a) *Identification.* A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a disease primarily of the lymph system).

(b) *Classification.* Class II.

§ 862.1195 Corticoids test system.

(a) *Identification.* A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and plasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(b) *Classification.* Class I.

§ 862.1200 Corticosterone test system.

(a) *Identification.* A corticosterone test system is a device intended to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

(b) *Classification.* Class I.

§ 862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

(a) *Identification.* A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

(b) *Classification.* Class II.

§ 862.1210 Creatine test system.

(a) *Identification.* A creatine test system is a device intended to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

(b) *Classification.* Class I.

§ 862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system.

(a) *Identification.* A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II.

§ 862.1225 Creatinine test system.

(a) *Identification.* A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

(b) *Classification.* Class II.

§ 862.1230 Cyclic AMP test system.

(a) *Identification.* A cyclic AMP test system is a device intended to measure the level of adenosine 3≠, 5≠-monophosphate (cyclic AMP) in plasma, urine, and other body fluids. Cyclic AMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium.)

(b) *Classification.* Class II.

§ 862.1240 Cystine test system.

(a) *Identification.* A cystine test system is a device intended to measure the amino acid cystine in urine. Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

(b) *Classification.* Class I.

§ 862.1245 Dehydroepiandrosterone (free and sulfate) test system.

(a) *Identification.* A dehydroepiandrosterone (free and sulfate) test system is a device intended to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

(b) *Classification.* Class I.

§ 862.1250 Desoxycorticosterone test system.

(a) *Identification.* A desoxycorticosterone test system is a device intended to measure desoxycorticosterone (DOC) in plasma and urine. DOC measurements are used in the diagnosis and treatment of patients with hypermineralocorticoidism (excess retention of sodium and loss of potassium) and other disorders of the adrenal gland.

(b) *Classification.* Class I.

§ 862.1255 2,3-Diphosphoglyceric acid test system.

(a) *Identification.* A 2,3-diphosphoglyceric acid test system is a device intended to measure 2,3-diphosphoglyceric acid (2,3-DPG) in erythrocytes (red blood cells). Measurements of 2,3-diphosphoglyceric acid are used in the diagnosis and treatment of blood disorders that affect the delivery of oxygen by erythrocytes to tissues and in monitoring the quality of stored blood.

(b) *Classification.* Class I.

§ 862.1260 Estradiol test system.

(a) *Identification.* An estradiol test system is a device intended to measure

estradiol, an estrogenic steroid, in plasma. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

(b) *Classification.* Class I.

§ 862.1265 Estriol test system.

(a) *Identification.* An estriol test system is a device intended to measure estriol, an estrogenic steroid, in plasma, serum, and urine of pregnant females. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

§ 862.1270 Estrogens (total, in pregnancy) test system.

(a) *Identification.* As estrogens (total, in pregnancy) test system is a device intended to measure total estrogens in plasma, serum, and urine during pregnancy. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used to aid in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

§ 862.1275 Estrogens (total, nonpregnancy) test system.

(a) *Identification.* As estrogens (total, nonpregnancy) test system is a device intended to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses) differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

§ 862.1280 Estrone test system.

(a) *Identification.* An estrone test system is a device intended to measure estrone, an estrogenic steroid, in plasma. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

§ 862.1285 Etiocholanolone test system.

(a) *Identification.* As etiocholanolone test system is a device intended to measure etiocholanolone in serum and urine. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

(b) *Classification.* Class I.

§ 862.1290 Fatty acids test system.

(a) *Identification.* A fatty acids test system is a device intended to measure fatty acids in plasma and serum. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

(b) *Classification.* Class I.

§ 862.1295 Folic acid test system.

(a) *Identification.* A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

(b) *Classification.* Class I.

§ 862.1300 Follicle-stimulating hormone test system.

(a) *Identification.* A follicle-stimulating hormone test system is a device intended to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.

(b) *Classification.* Class I.

§ 862.1305 Formiminoglutamic acid (FIGLU) test system.

(a) *Identification.* A formiminoglutamic acid (FIGLU) test system is a device intended to measure formiminolutamic acid in urine. FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

(b) *Classification.* Class I.

§ 862.1310 Galactose test system.

(a) *Identification.* A galactose test system is a device intended to measure galactose in blood and urine. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification.* Class I.

§ 862.1315 Galactose-1-phosphate uridyl transferase test system.

(a) *Identification.* A galactose-1-phosphate uridyl transferase test system is a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

(b) *Classification.* Class II.

§ 862.1320 Gastric acidity test system.

(a) *Identification.* A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(b) *Classification.* Class I.

§ 862.1325 Gastrin test system.

(a) *Identification.* A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(b) *Classification.* Class I.

§ 862.1330 Globulin test system.

(a) *Identification.* A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(b) *Classification.* Class I.

§ 862.1335 Glucagon test system.

(a) *Identification.* A glucagon test system is a device intended to measure pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class I.

§ 862.1340 Urinary glucose (nonquantitative) test system.

(a) *Identification.* A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II.

§ 862.1345 Glucose test system.

(a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) *Classification.* Class II.

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) *Identification.* A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(b) *Classification.* Class I.

§ 862.1365 Glutathione test system.

(a) *Identification.* A glutathione test system is a device intended to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells). Glutathione measurements are used in the diagnosis and treatment of certain drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.

(b) *Classification.* Class I.

§ 862.1370 Human growth hormone test system.

(a) *Identification.* A human growth hormone test system is a device intended to measure the levels of human growth hormone in plasma. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.

(b) *Classification.* Class I.

§ 862.1375 Histidine test system.

(a) *Identification.* A histidine test system is a device intended to measure free histidine (an amino acid) in plasma and urine. Histidine measurements are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

(b) *Classification.* Class I.

§ 862.1377 Urinary homocystine (nonquantitative) test system.

(a) *Identification.* A urinary homocystine (nonquantitative) test system is a device intended to identify homocystine (an analogue of the amino acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homosystine in urine), a heritable metabolic disorder which may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1380 Hydroxybutyric dehydrogenase test system.

(a) *Identification.* A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

(b) *Classification.* Class I.

§ 862.1385 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.

(a) *Identification.* A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device intended to measure corticosteroids that possess a dihydroxyacetone ($HOCH_2$—C CH_2OH) moiety on the steroid nucleus in urine. —— O

Corticosteroids with this chemical configuration include cortisol, cortisone 11-desoxycortisol, desoxycorticosterone, and their tetrahydroderivatives. This group of hormones is synthesized by the adrenal gland. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.

(b) *Classification.* Class I.

§ 862.1390 5-Hydroxyindole acetic acid/serotonin test system.

(a) *Identification.* A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

(b) *Classification.* Class I.

§ 862.1395 17-Hydroxyprogesterone test system.

(a) *Identification.* A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) *Classification.* Class I.

§ 862.1400 Hydroxyproline test system.

(a) *Identification.* A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone diseass such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

(b) *Classification.* Class I.

§ 862.1405 Immunoreactive insulin test system.

(a) *Identification.* An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.

(b) *Classification.* Class I.

§ 862.1410 Iron (non-heme) test system.

(a) *Identification.* An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

(b) *Classification.* Class I.

§ 862.1415 Iron-binding capacity test system.

(a) *Identification.* An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(b) *Classification.* Class I.

§ 862.1420 Isocitric dehydrogenase test system.

(a) *Identification.* An isocitric dehydrogenase test system is a device intended to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma. Isocitric dehydrogenase measurements are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply

to the lungs), and diseases associated with pregnancy.

(b) *Classification.* Class I.

§ 862.1430 17-Ketosteroids test system.

(a) *Identification.* A 17-ketosteroids test system is a device intended to measure 17-ketosteroids in urine. Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

(b) *Classification.* Class I.

§ 862.1435 Ketones (nonquantitative) test system.

(a) *Identification.* A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

(b) *Classification.* Class I.

§ 862.1440 Lactate dehydrogenase test system.

(a) *Identification.* A lactate dehydrogenase test system is a device intended to measure the activity of the enzyme lactate dehydrogenase in serum. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

(b) *Classification.* Class II.

§ 862.1445 Lactate dehydrogenase isoenzymes test system.

(a) *Identification.* A lactate dehydrogenase isoenzymes test system is a device intended to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum. Measurements of lactate dehydrogenase isoenzymes are used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.

(b) *Classification.* Class II.

§ 862.1450 Lactic acid test system.

(a) *Identification.* A lactic acid test system is a device intended to measure lactic acid in whole blood and plasma. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

(b) *Classification.* Class I.

§ 862.1455 Lecithin/sphingomyelin ratio in amniotic fluid test system.

(a) *Identification.* A lecithin/sphingomyelin ratio in amniotic fluid test system is a device intended to measure the lecithin/sphingomyelin ratio in amniotic fluid. Lecithin and sphingomyelin are phospholipids (fats or fat-like substances containing phosphorus). Measurements of the lecithin/sphingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

(b) *Classification.* Class II.

§ 862.1460 Leucine aminopeptidase test system.

(a) *Identification.* A leucine aminopeptidase test system is a device intended to measure the activity of the enzyme leucine amino-peptidase in serum, plasma, and urine. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.

(b) *Classification.* Class I.

§ 862.1465 Lipase test system.

(a) *Identification.* A lipase test system is a device intended to measure the activity of the enzymes lipase in serum. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

(b) *Classification.* Class I.

§ 862.1470 Lipid (total) test system.

(a) *Identification.* A lipid (total) test system is a device intended to measure total lipids (fats or fat-like substances) in serum and plasma. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

(b) *Classification.* Class I.

§ 862.1475 Lipoprotein test system.

(a) *Identification.* A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

(b) *Classification.* Class I.

§ 862.1485 Luteinizing hormone test system.

(a) *Identification.* A luteinizing hormone test system is a device intended to measure luteinizing hormone in serum and urine. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.

(b) *Classification.* Class I.

§ 862.1490 Lysozyme (muramidase) test system.

(a) *Identification.* A lysozyme (muramidase) test system is a device intended to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine. Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.

(b) *Classification.* Class I.

§ 862.1495 Magnesium test system.

(a) *Identification.* A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

(b) *Classification.* Class I.

§ 862.1500 Malic dehydroqenase test system.

(a) *Identification.* A malic dehydrogenase test system is a device that is intended to measure the activity of the enzyme malic dehydrogenase in serum and plasma. Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemia.

(b) *Classification.* Class I.

§ 862.1505 Mucopolysaccharides (nonquantitative) test system.

(a) *Identification.* A mucopolysaccharides (nonquantitative) test system is a device intended to measure the levels of mucopolysaccharides in urine. Mucopolysaccharide measurements in urine are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's, Sanfilippo's, Scheie's Morquio's and Maroteaux-Lamy syndromes.

(b) *Classification.* Class I.

§ 862.1509 Methylmalonic acid (nonquantitative) test system.

(a) *Identification.* A methylmalonic acid (nonquantitative) test system is a device intended to identify methylmalonic acid in urine. The identification of methylmalonic acid in urine is used in the diagnosis and

treatment of methylmalonic aciduria, a heritable metabolic disorder which, if untreated, may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1510 Nitrite (nonquantitative) test system.

(a) *Identification.* A nitrite (nonquantitative) test system is a device intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of uninary tract infection of bacterial origin.

(b) *Classification.* Class I.

§ 862.1515 Nitrogen (amino-nitrogen) test system.

(a) *Identification.* A nitrogen (amino-nitrogen) test system is a device intended to measure amino acid nitrogen levels in serum, plasma, and urine. Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver diseases and renal disorders.

(b) *Classification.* Class I.

§ 862.1520 A 5'-Nucleotidase test system.

(a) *Identification.* A 5'-nucleotidase test system is a device intended to measure the activity of the enzyme 5'-nucleotidase in serum and plasma. Measurements of 5'-nucleotidase are used in the diagnosis and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.

(b) *Classification.* Class I.

§ 862.1530 Plasma oncometry test system.

(a) *Identification.* A plasma oncometry test system is a device intended to measure plasma oncotic pressure. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock.

(b) *Classification.* Class I.

§ 862.1535 Ornithine carbamyl transferase test system.

(a) *Identification.* An ornithine carbamyl transferase test system is a device intended to measure the activity of the enzyme ornithine carbamyl transferase (OCT) in serum. Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.

(b) *Classification.* Class I.

§ 862.1540 Osmolality test system.

(a) *Identification.* An osmolality test system is a device intended to measure ionic and nonionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.

(b) *Classification.* Class I.

§ 862.1542 Oxalate test system.

(a) *Identification.* An oxalate test system is a device intended to measure the concentration of oxalate in urine. Measurements of oxalate are used to aid in the diagnosis or treatment of urinary stones or certain other metabolic disorders.

(b) *Classification.* Class I.

§ 862.1545 Parathyroid hormone test system.

(a) *Identification.* A parathyroid hormone test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

(b) *Classification.* Class II.

§ 862.1550 Urinary pH (nonquantitative) test system.

(a) *Identification.* A urinary pH (nonquantitative) test system is a device intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

(b) *Classification.* Class I.

§ 862.1555 Phenylalanine test system.

(a) *Identification.* A phenylalanine test system is a device intended to measure free phenylalanine (an amino acid) in serum, plasma, and urine. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1560 Urinary phenylketones (nonquantitative) test system.

(a) *Identification.* A urinary phenylketones (nonquantitative) test system is a device intended to identify phenylketones (such as phenylpyruvic acid) in urine. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class I.

§ 862.1565 6-Phosphogluconate dehydrogenase test system.

(a) *Identification.* A 6-phosphogluconate dehydrogenase test system is a device intended to measure the activity of the enzyme 6-phosphogluconate dehydrogenase (6 PGD) in serum and erythrocytes. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.

(b) *Classification.* Class I.

§ 862.1570 Phosphohexose isomerase test system.

(a) *Identification.* A phosphohexose isomerase test system is a device intended to measure the activity of the enzyme phosphohexose isomerase in serum. Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.

(b) *Classification.* Class I.

§ 862.1575 Phospholipid test system.

(a) *Identification.* A phospholipid test system is a device intended to measure phospholipids in serum and plasma. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.

(b) *Classification.* Class I.

§ 862.1580 Phosphorus (inorganic) test system.

(a) *Identification.* A phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

(b) *Classification.* Class I.

§ 862.1585 Human placental lactogen test system.

(a) *Identification.* A human placental lactogen test system is a device intended to measure the hormone

human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)), in maternal serum and maternal plasma. Measurements of human placental lactogen are used in the diagnosis and clinical management of high-risk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency, or possible miscarriage.

(b) *Classification.* Class II.

§ 862.1590 Porphobilinogen test system.

(a) *Identification.* A porphobilinogen test system is a device intended to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrine metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1595 Porphyrins test system.

(a) *Identification.* A porphyrins test system is a device intended to measure porphyrins (compounds formed during the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1600 Potassium test system.

(a) *Identification.* A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

(b) *Classification.* Class II.

§ 862.1605 Pregnanediol test system.

(a) *Identification.* A pregnanediol test system is a device intended to measure pregnanediol (a major urinary metabolic product of progesterone) in urine. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

§ 862.1610 Pregnanetriol test system.

(a) *Identification.* A pregnanetriol test system is a device intended to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).

(b) *Classification.* Class I.

§ 862.1615 Pregnenolone test system.

(a) *Identification.* A pregnenolone test system is a device intended to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.

(b) *Classification.* Class I.

§ 862.1620 Progesterone test system.

(a) *Identification.* A progesterone test system is a device intended to measure progesterone (a female hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

§ 862.1625 Prolactin (lactogen) test system.

(a) *Identification.* A prolactin (lactogen) test system is a device intended to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

(b) *Classification.* Class I.

§ 862.1630 Protein (fractionation) test system.

(a) *Identification.* A Protein (fractionation) test system is a device intended to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids. Protein fractionations are used as a aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.

(b) *Classification.* Class I.

§ 862.1635 Total protein test system.

(a) *Identification.* A total protein test system is a device intended to measure total protein(s) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

(b) *Classification.* Class II.

§ 862.1640 Protein-bound iodine test system.

(a) *Identification.* A protein-bound iodine test system is a device intended to measure protein-bound iodine in serum. Measurements of protein-bound iodine obtained by this device are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class I.

§ 862.1645 Urinary protein or albumin (nonquantitative) test system.

(a) *Identification.* A urinary protein or albumin (nonquantitative) test system is a device intended to identify proteins or albumin in urine. Identification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.

(b) *Classification.* Class I.

§ 862.1650 Pyruvate kinase test system.

(a) *Identification.* A pyruvate kinase test system is a device intended to measure the activity of the enzyme pyruvate kinase in erythrocytes (red blood cells). Measurements obtained by this device are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias.

(b) *Classification.* Class I.

§ 862.1655 Pyruvic acid test system.

(a) *Identification.* A pyruvic acid test system is a device intended to measure pyruvic acid (an intermediate compound in the metabolism of carbohydrate) in plasma. Measurements obtained by this device are used in the evaluation of electrolyte metabolism and in the diagnosis and treatment of acid-base and electrolyte disturbances or anoxia (the reduction of oxygen in body tissues).

(b) *Classification.* Class I.

§ 862.1660 Quality control material (assayed and unassayed).

(a) *Identification.* A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single

(specified) analytes, or urinalysis controls.

(b) *Classification.* Class I.

§ 862.1665 Sodium test system.

(a) *Identification.* A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

(b) *Classification.* Class II.

§ 862.1670 Sorbitol dehydrogenase test system.

(a) *Identification.* A sorbitol dehydrogenase test system is a device intended to measure the activity of the enzyme sorbitol dehydrogenase in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

(b) *Classification.* Class I.

§ 862.1675 Blood specimen collection device.

(a) *Identification.* A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

(b) *Classification.* Class II.

§ 862.1680 Testosterone test system.

(a) *Identification.* A testosterone test system is a device intended to measure testosterone (a male sex hormone) in serum, plasma, and urine. Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

(b) *Classification.* Class I (general controls).

§ 862.1685 Thyroxine-binding globulin test system.

(a) *Identification.* A thyroxine-binding globulin test system is a device intended to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1690 Thyroid stimulating hormone test system.

(a) *Identification.* A thyroid stimulating hormone test system is a device intended to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

(b) *Classification.* Class II.

§ 862.1695 Free thyroxine test system.

(a) *Identification.* A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in serum and plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1700 Total thyroxine test system.

(a) *Identification.* A total thyroxine test system is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1705 Triglyceride test system.

(a) *Identification.* A triglyceride test system is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(b) *Classification.* Class I.

§ 862.1695 Free thyroxine test system.

(a) *Identification.* A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in serum or plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1700 Total thyroxine test system.

(a) *Identification.* A total thyroxine test system is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1705 Triglyceride test system.

(a) *Identification.* A triglyceride test system is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(b) *Classification.* Class I.

§ 862.1710 Total triiodothyronine test system.

(a) *Identification.* A total triiodothyronine test system is a device intended to measure the hormone triiodothyronine in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

(b) *Classification.* Class II.

§ 862.1715 Triiodothyronine uptake test system.

(a) *Identification.* A triiodothyronine uptake test system is a device intended to measure the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thyrkoxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class II.

§ 862.1720 Triose phosphate isomerase test system.

(a) *Identification.* A triose phosphate isomerase test system is a device intended to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells). Triose phosphate isomerase is an enzyme important in glycolysis (the energy-yielding conversion of glucose to lactic acid in various tissues). Measurements

obtained by this device are used in the diagnosis and treatment of congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia.

(b) *Classification.* Class II.

§ 862.1725 Trypsin test system.

(a) *Identification.* A trypsin test system is a device intended to measure the activity of trypsin (a pancreatic enzyme important in digestion for the breakdown of proteins) in blood and other body fluids and in feces. Measurements obtained by this device are used in the diagnosis and treatment of pancreatic disease.

(b) *Classification.* Class I.

§ 862.1730 Free tyrosine test system.

(a) *Identification.* A free tyrosine test system is a device intended to measure free tyrosine (an amono acid) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia (a disease that can cause liver/kidney disorders) and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria (a disease that can cause brain damage).

(b) *Classification.* Class I.

§ 862.1770 Urea nitrogen test system.

(a) *Identification.* A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

(b) *Classification.* Class II.

§ 862.1775 Uric acid test system.

(a) *Identification.* A uric acid test system is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

(b) *Classification.* Class I.

§ 862.1780 Urinary calculi (stones) test system.

(a) *Identification.* A urinary calculi (stones) test system is a device intended for the analysis of urinary calculi. Analysis of urinary calculi is used in the diagnosis and treatment of calculi of the urinary tract.

(b) *Classification.* Class I.

§ 862.1785 Urinary urobilinogen (nonquantitative) test system.

(a) *Identification.* A urinary urobilinogen (nonquantitative) test system is a device intended to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cells) disorders.

(b) *Classification.* Class I.

§ 862.1790 Uroporphyrin test system.

(a) *Identification.* A uroporphyrin test system is a device intended to measure uroporphyrin in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1795 Vanilmandelic acid test system.

(a) *Identification.* A vanilmandelic acid test system is a device intended to measure vanilmandelic acid in urine. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.

(b) *Classification.* Class I.

§ 862.1805 Vitamin A test system.

(a) *Identification.* A vitamin A test system is a device intended to measure vitamin A in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.

(b) *Classification.* Class I.

§ 862.1810 Vitamin B_{12} test system.

(a) *Identification.* A vitamin B_{12} test system is a device intended to measure vitamin B_{12} in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

(b) *Classification.* Class II.

§ 862.1815 Vitamin E test system.

(a) *Identification.* A vitamin E test system is a device intended to measure vitamin E (tocopherol) in serum. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.

(b) *Classification.* Class I.

§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(b) *Classification.* Class I.

Subpart C—Clinical Laboratory Instruments

§ 862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.

(a) *Identification.* General purpose laboratory equipment labeled or promoted for a specific medical use is a device that is intended to prepare or examine specimens from the human body and that is labeled or promoted for a specific medical use.

(b) *Classification.* Class I. The device identified in paragraph (a) of this section is exempt from the premarket notification procedures in Subpart E of Part 807 and is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

(b) *Classification.* Class I.

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

(a) *Identification.* A centrifugal chemistry analyzer for clinical use is an automatic device intended to centrifugally mix a sample and a reagent and spectrophotometrically measure concentrations of the sample constituents. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I.

§ 862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

(a) *Identification.* A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument intended to simultaneously perform multiple chemical procedures using the principles of automated

continuous flow systems. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I.

§ 862.2160 Discrete photometric chemistry analyzer for clinical use.

(a) *Identification.* A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

(b) *Classification.* Class I.

§ 862.2170 Microchemistry analyzer for clinical use.

(a) *Identification.* A micro chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volume samples obtainable from pediatric patients. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I.

§ 862.2230 Chromatographic separation material for clinical use.

(a) *Identification.* A chromatographic separation material for clinical use is a device accessory (e.g., ion exchange absorbents, ion exchagne resins, and ion papers) intended for use in ion exchange chromatography, a procedure in which a compound is separated from a solution.

(b) *Classification.* Class I.

§ 862.2250 Gas liquid chromatography system for clinical use.

(a) *Identification.* A gas liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports, and liquid coating.

(b) *Classification.* Class I.

§ 862.2260 High pressure liquid chromatography system for clinical use.

(a) *Identification.* A high pressure liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.

(b) *Classification.* Class I.

§ 862.2270 Thin-layer chromatography system for clinical use.

(a) *Identification.* A thin-layer chromatography (TLC) system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.

(b) *Classification.* Class I. Particular components of TLC systems, i.e., the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.

(a) *Identification.* A colorimeter, a photometer, or a spectrophotometer for clinical use is an instrument intended to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions. The device may include a monochromator to produce light of a specific wavelength.

(b) *Classification.* Class I.

§ 862.2310 Clinical sample concentrator.

(a) *Identification.* A clinical sample concentrator is a device intended to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed.

(b) *Classification.* Class I.

§ 862.2320 Beta or gamma counter for clinical use.

(a) *Identification.* A beta or gamma counter for clinical use is a device intended to detect and count beta or gamma radiation emitted by clinical samples. Clinical samples are prepared by addition of a radioactive reagent to the sample. These measurements are useful in the diagnosis and treatment of various disorders.

(b) *Classification.* Class I.

§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

(a) *Identification.* A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is device intended to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radio-active element on a radiochromatogram.

(b) *Classification.* Class I.

§ 862.2485 Electrophoresis apparatus for clinical use.

(a) *Identification.* An electrophoresis apparatus for clinical use is a device intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.

(b) *Classification.* Class I.

§ 862.2500 Enzyme analyzer for clinical use.

(a) *Identification.* An enzyme analyzer for clinical use is a device intended to measure enzymes in plasma or serum by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme-related disorders.

(b) *Classification.* Class I.

§ 862.2540 Flame emission photometer for clinical use.

(a) *Identification.* A flame emission photometer for clinical use is a device intended to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.

(b) *Classification.* Class I.

§ 862.2560 Fluorometer for clinical use.

(a) *Identification.* A fluorometer for clinical use is a device intended to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I.

§ 862.2680 Microtitrator for clinical use.

(a) *Identification.* A microtitrator for clinical use is a device intended for use in micronanalysis to measure the concentration of a substance by reacting it with a measure "micro" volume of a known standardization solution.

(b) *Classification.* Class I.

§ 862.2700 Nephelometer for clinical use.

(a) *Identification.* A nephelometer for clinical use is a device intended to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

(b) *Classification.* Class I.

§ 862.2720 Plasma oncometer for clinical use.

(a) *Identification.* A plasma oncometer for clinical use is a device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders.

(b) *Classification.* Class I.

§ 862.2730 Osometer for clinical use.

(a) *Identification.* An osmometer for clinical use is a device intended to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.

(b) *Classification.* Class I.

§ 862.2750 Pipetting and diluting system for clinical use.

(a) *Identification.* A pipetting and diluting system for clinical use is a device intended to provide an accurately measured volume of liquid at a specified temperature for use in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

(b) *Classification.* Class I.

§ 862.2800 Refractometer for clinical use.

(a) *Identification.* A refractometer for clinical use is a device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such a plasma total proteins and urinary total solids. Measurements obtained by this device are use in the diagnosis and treatment of certain conditions.

(b) *Classification.* Class I.

§ 862.2850 Atomic absorption spectrophotometer for clinical use.

(a) *Identification.* An atomic absorption spectrophotometer for clinical use is a device intended to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(b) *Classification.* Class I.

§ 862.2860 Mass spectrometer for clinical use.

(a) *Identification.* A mass spectrometer for clinical use is a device intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and megnetic field according to their mass.

(b) *Classification.* Class I.

§ 862.2900 Automated urinalysis system.

(a) *Identification.* An automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.

(b) *Classification.* Class I.

§ 862.2920 Plasma viscometers for clinical use.

(a) *Identification.* A plasma viscometer for clinical use is a device intended to measure the viscosity of plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

(b) *Classification.* Class I.

Subpart D—Clinical Toxicology Test System

§ 862.3030 Acetaminophen test system.

(a) *Identification.* An acetaminophen test system is a device intended to measure acetaminophen, an analgestic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(b) *Classification.* Class II.

§ 862.3035 Amikacin test system.

(a) *Identification.* An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3040 Alcohol test system.

(a) *Identification.* An alcohol test system is a device intented to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) *Classification.* Class II.

§ 862.3050 Breath-alcohol test system.

(a) *Identification.* A breath-alcohol test system is a device intened to measure alcohol in the human breath. Measurements obtained by this device are used in the disgnosis of alcohol intoxication.

(b) *Classification.* Class I.

§ 862.3100 Amphetamine test system.

(a) *Identification.* An amphetamine test system is a device intended to measure amphetamine, a central

nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3110 Antimony test system.

(a) *Identification.* An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.

(b) *Classification.* Class I.

§ 862.3120 Arsenic test system.

(a) *Identification.* An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.

(b) *Classification.* Class I.

§ 862.3150 Barbiturate test system.

(a) *Identification.* A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturate to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3170 Benzodiazepine test system.

(a) *Identification.* A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, chlorzepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose and in monitoring levels of benzodiazepines to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3200 Clinical toxicology calibrator.

(a) *Identification.* A clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.). (See also § 862.2 in this part.)

(b) *Classification.* Class II.

§ 862.3220 Carbon monoxide test system.

(a) *Identification.* A carbon monoxide test system is a device intended to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.

(b) *Classification.* Class I.

§ 862.3240 Cholinesterase test system.

(a) *Identification.* A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) *Classification.* Class I.

§ 862.3250 Cocaine and cocaine metabolite test system.

(a) *Identification.* A cocaine and cocaine metabolite test system is a device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.

(b) *Classification.* Class II.

§ 862.3270 Codeine test system.

(a) *Identification.* A codeine test system is a device intended to measure codeine (a narcotic pain-relieving drug) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of codeine use or overdose and in monitoring levels of codeine to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3280 Clinical toxicology control material.

(a) *Identification.* A clinical toxicology control material is a device intended to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various single, and multi-analyte control materials.

(b) *Classification.* Class I.

§ 862.3300 Digitoxin test system.

(a) *Identification.* A digitoxin test system is a device intended to measure digitoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3320 Digoxin test system.

(a) *Identification.* A digoxin test system is a device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3350 Diphenylhydantoin test system.

(a) *Identification.* A diphenylhydantoin test system is a device intended to measure diphenylhydantoin, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3380 Ethosuximide test system.

(a) *Identification.* An ethosuximide test system is a device intended to measure ethosuximide, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of ethosuximide overdose and in monitoring levels of ethosuximide to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3450 Gentamicin test system.

(a) *Identification.* A gentamicin test system is a device intended to measure gentamicin, an antibiotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3520 Kanamycin test system.

(a) *Identification.* A kanamycin test system is a device intended to measure kanamycin, an antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in

monitoring levels of kanamycin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3550 Lead test system.

(a) *Identification.* A lead test system is a device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.

(b) *Classification.* Class II.

§ 862.3555 Lidocaine test system.

(a) *Identification.* A lidocaine test system is a device intended to measure lidocaine, an antiarrythmic and anticonvulsant drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of lidocaine overdose or in monitoring levels of lidocaine to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3560 Lithium test system.

(a) *Identification.* A lithium test system is a device intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

(b) *Classification.* Class II.

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

(a) *Identification.* A lysergic acid diethylamide (LSD) test system is a device intended to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of LSD use or overdose.

(b) *Classification.* Class II.

§ 862.3600 Mercury test system.

(a) *Identification.* A mercury test system is a device intended to measure mercury, a heavy metal, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.

(b) *Classification.* Class I.

§ 862.3610 Methamphetamine test system.

(a) *Identification.* A methamphetamine test system is a device intended to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine use or overdose.

(b) *Classification.* Class II.

§ 862.3620 Methadone test system.

(a) *Identification.* A methadone test system is a device intended to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone use or overdose and to determine compliance with regulations in methadone maintenance treatment.

(b) *Classification.* Class II.

§ 862.3630 Methaqualone test system.

(a) *Identification.* A methaqualone test system is a device intended to measure methaqualone, a hypnotic and sedative drug, in urine. Measurements obtained by this device are used in the diagnosis and treatment of methaqualone use or overdose.

(b) *Classification.* Class II.

§ 862.3640 Morphine test system.

(a) *Identification.* A morphine test system is a device intended to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of morphine use or overdose and in monitoring levels of morphine and its analogs to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3645 Neuroleptic drugs radioreceptor assay test system.

(a) *Identification.* A neuroleptic drugs radioceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of such drugs.

(b) *Classification.* Class II.

§ 862.3650 Opiate test system.

(a) *Identification.* An opiate test system is a device intended to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmocological actions. The opiates include drugs such as morphine, morphine glucoronide, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3660 Phenobarbital test system.

(a) *Identification.* A phenobarbitol test system is a device intended to measure phenobarbital, and antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3670 Phenothiazine test system.

(a) *Identification.* A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.

(b) *Classification.* Class II.

§ 862.3680 Primidone test system.

(a) *Identification.* A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3700 Propoxyphene test system.

(a) *Identification.* A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3750 Quinine test system.

(a) *Identification.* A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) *Classification.* Class II.

§ 862.3830 Salicylate test system.

(a) *Identification.* A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human

specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3850 Sulfonamide test system.

(a) *Identification.* A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.

(b) *Classification.* Class I.

§ 862.3870 Cannabinoid test system.

(a) *Identification.* A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marihuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.

(b) *Classification.* Class II.

§ 862.3880 Theophylline test system.

(a) *Identification.* A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3900 Tobramycin test system.

(a) *Identification.* A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3910 Tricyclic antidepressant drugs test system.

(a) *Identification.* A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3950 Vancomycin test system.

(a) *Identification.* A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

(b) *Classification.* Class II.

Dated: April 3, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-9858 Filed 4-30-87; 8:45 am]

BILLING CODE 4160-01-M