(f) This amendment becomes effective on January 6, 1995.

Issued in Renton, Washington, on November 23, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–29437 Filed 12–6–94; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 39

[Docket No. 94–NM–199–AD; Amendment 39–9086; AD 94–25–02]

Airworthiness Directives; Jetstream Model ATP Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Jetstream Model ATP airplanes. This action requires inspections to detect cracking in certain oil coolers, and replacement of cracked coolers with serviceable coolers. The amendment also provides for termination of the inspections by installing certain reworked and re-identified oil coolers. This amendment is prompted by reports of cracking in the welded seams of certain oil coolers. The actions specified in this AD are intended to prevent loss of engine oil due to cracking in the oil cooler, which may lead to a forced shutdown of the engine.

DATES: Effective December 22, 1994.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 22, 1994.

Comments for inclusion in the Rules Docket must be received on or before February 6, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–199–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–2148; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Jetstream Model ATP airplanes. The CAA advises that it has received reports of cracking in the welded seams of certain engine oil coolers that are cooled by ram air. Investigation revealed that these oil coolers were welded incorrectly during the manufacturing process. These defective welds have been isolated to oil coolers manufactured by Normalair-Garrett Limited and having part numbers (P/N) 8248C000, 8439C000, and 8714C000. Such cracking, if not corrected, could result in loss of engine oil, which may lead to a forced shutdown of the engine.

Jetstream has issued Service Bulletin ATP–79–23, dated August 26, 1994, which describes procedures for repetitive detailed visual inspections to detect cracking in certain engine oil coolers that are cooled by ram air. This service bulletin also describes procedures for replacement of cracked oil coolers with serviceable oil coolers. The CAA classified this service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom.

Jetstream has also issued Service Bulletin ATP–79–24–10360A, dated September 4, 1994, which describes procedures for rework and re-identification of oil coolers having P/N's 8248C000, 8439C000, and 8714C000, that are manufactured by Normalair-Garrett Limited.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent loss of engine oil that may lead to a forced shutdown of the engine. This AD requires repetitive detailed visual inspections to detect cracking in oil coolers having P/N 8248C000, 8439C000, or 8714C000, and replacement of cracked oil coolers with serviceable oil coolers. Installation of oil coolers that have been reworked and re-identified terminates the requirement for repetitive detailed visual inspections. The actions are required to be accomplished in accordance with the service bulletins described previously.

As a result of recent communications with the Air Transport Association (ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this final rule to clarify this requirement.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 94–NM–199–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–25–02 Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Amendment 39–9086. Docket 94–NM–199–AD.

Applicability: Model ATP airplanes having constructor's numbers 2002 through 2063, inclusive; and equipped with Normalair-Garrett Limited oil coolers having part number 8248C000, 8439C000, or 8714C000; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of engine oil that may lead to a forced shutdown of the engine, accomplish the following:

(a) Prior to the accumulation of 2,000 total landings on the engine oil cooler that is cooled by ram air on the left and right engine, or within 50 hours time-in-service after the effective date of this AD, whichever occurs later, perform a detailed visual inspection to detect cracking in the oil cooler, in accordance with British Aerospace Service Bulletin ATP–79–23, dated August 26, 1994.

(1) If no cracking is detected, repeat this inspection thereafter at intervals not to exceed 75 hours time-in-service.

(2) If any cracking is detected, prior to further flight, replace the oil cooler with a serviceable oil cooler having either part number (P/N) 8439C000–002 or 8714C000–002, in accordance with British Aerospace Service Bulletin ATP–79–23, dated August 26, 1994, or with an oil cooler than has been reworked and re-identified in accordance with British Aerospace Service Bulletin ATP–79–24–10360A, dated September 4, 1994.

(b) Installation of an oil cooler that has been reworked and re-identified as either P/N 8714C000–002 or 8439C000–002, in accordance with British Aerospace Service Bulletin ATP–79–24–10360A, dated September 4, 1994, constitutes terminating action for the inspection requirements of this AD.

Note 2: Reworked oil coolers have an initial life limit of 9,000 landings. This life limit and any changes to it are specified in the Limitations Section in Chapter 5 of the ATP Maintenance Manual.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspection shall be done in accordance with Jetstream Service Bulletin ATP–79–23, dated August 26, 1994, and the rework and re-identification shall be done in accordance with Jetstream Service Bulletin ATP–79–24–10360A, dated September 4, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 22, 1994.

Issued in Renton, Washington, on November 30, 1994.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–29918 Filed 12–6–94; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 39

[Docket No. 94–NM–207–AD; Amendment 39–9085; AD 94–25–01]

Airworthiness Directives; Boeing Model 747 Series Airplanes Equipped with Pratt & Whitney Model JT9D–70 Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Model 747 series airplanes. This action requires inspections to detect cracking of the surfaces of the outboard strut spring beam, and replacement of cracked spring beams. It also requires an inspection to detect damage to the structure that is adjacent to the cracked spring beam, and replacement of any cracked parts. This amendment is prompted by a report of failure of a spring beam due to cracking that was propagated by fatigue. The actions specified in this AD are intended to prevent failure of a spring beam, which could lead to loss of an outboard strut.

DATES: Effective on December 22, 1994.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 22, 1994.

Comments for inclusion in the Rules Docket must be received on or before February 6, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–207–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2776; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: Recently, the FAA received a report that the spring beam on a Boeing Model 747–200 series airplane equipped with Pratt & Whitney (P&W) Model JT9D–70 engines was severed (failed) forward of the mid pivot bolt housing at the outboard spring beam on the number 4 outboard strut. Investigation revealed that cracking initiated at a flaw (porosity) in the material of the spring beam and propagated due to fatigue. The subject airplane was operated as a freighter and had accumulated 15,809 total flight cycles on the struts. This airplane was originally delivered with P&W Model JT9D–3 engines and struts, but was later reconfigured with P&W Model JT9D–70 engines and struts.

Spring beams are used in place of midspar fittings on the outboard struts of all Model 747 series airplanes, except those equipped with P&W Model JT9D–3 and –7 engines. (The P&W Model JT9D–3 and –7 engines have midspar fittings at the outboard strut.) Airplanes equipped with P&W Model JT9D–70 engines have spring beams that are made of titanium. All other spring beams are made of steel, which analyses and tests have shown to be more resistant to fatigue cracking than titanium spring beams.

Fatigue cracking, if not corrected, could result in failure of a spring beam, which could lead to the loss of an outboard strut.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994, which describes procedures for repetitive detailed visual inspections to detect cracking of the upper, lower, and side surfaces of the spring beam, and replacement of cracked spring beams with new spring beams.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to prevent failure of a spring beam due to fatigue cracking, which could lead to the loss of an outboard strut. This AD requires repetitive detailed visual inspections to detect cracking of the surfaces of the spring beam from the root of the clevis lugs to the forward journal, and replacement of cracked spring beams with new spring beams. This AD also requires an additional detailed visual inspection to detect damage of the adjacent spring beam and all support fittings of the affected strut, and replacement of any cracked parts with new parts. The actions are required to be accomplished in accordance with the alert service bulletin described previously.

As an alternative to the repetitive detailed visual inspections, this AD also provides for an optional terminating action, which entails removing the spring beam, accomplishing a fluorescent dye penetrant inspection, and accomplishing a zero-time overhaul of the spring beam, in accordance with Section 54–00–01 of the Boeing Overhaul Manual, and reinstalling that spring beam.

As a result of recent communications with the Air Transport Association (ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this rule to clarify this requirement.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following

statement is made: "Comments to Docket Number 94–NM–207–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–25–01 Boeing: Amendment 39–9085. Docket 94–NM–207–AD.

Applicability: Model 747 series airplanes having line numbers 202 through 396 inclusive, equipped with Pratt & Whitney Model JT9D–70 engines, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of a spring beam, which could lead to the loss of an outboard strut, accomplish the following:

(a) Prior to the accumulation of 10,000 total flight cycles or within 30 days after the effective date of this AD, whichever occurs later, perform a detailed visual inspection to detect cracking of the upper, lower, and side surfaces of the spring beam from the root of the clevis lugs to the forward journal, in accordance with Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994. (Remove the gap covers and fairing access panels to perform this inspection.)

Note 2: The area of inspection is illustrated in Figure 3 of the service bulletin.

(1) If no cracking is detected, repeat the inspection thereafter at intervals not to exceed 300 flight cycles.

(2) If any cracking is detected, prior to further flight, accomplish the requirements of paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this AD, in accordance with the service bulletin.

(i) Replace the cracked spring beam with a new spring beam.

(ii) Perform the detailed visual inspection required by paragraph (a) of this AD to detect cracking of the other spring beam on the affected strut. Also perform a detailed visual inspection to detect damage of all spring beam support fittings of the affected strut. Prior to further flight, replace any cracked or damaged parts with new parts.

(iii) Repeat the inspection of the surfaces of the spring beam required by paragraph (a) of this AD thereafter at intervals not to exceed 300 flight cycles.

(b) Accomplishment of all of the following actions in accordance with Boeing Overhaul Manual, Section 54–00–01, constitutes terminating action for the requirements of this AD.

(1) Remove the spring beam.

(2) Accomplish a fluorescent dye penetrant inspection.

(3) Zero-time overhaul the spring beam.

(4) Reinstall that spring beam.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The inspections and replacement shall be done in accordance with Boeing Alert Service Bulletin 747–54A2171, dated October 31, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 22, 1994.

Issued in Renton, Washington, on November 30, 1994.

James V. Devany, Acting Manager,

Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–29919 Filed 12–6–94; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. 94M–0260]

Medical Devices; Exemptions From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting 148 generic types of class I devices from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow

the agency to make better use of its resources and thus better serve the public.

DATES: Effective January 6, 1995. Beginning on January 6, 1995, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category which is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the act.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765 ext. 157.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 21, 1994 (59 FR 37378), FDA issued a proposed rule to exempt 164 generic types of class I devices from the requirement of premarket notification, with limitations. Interested persons were given until October 19, 1994 to comment on the proposed rule.

II. Comments

During the comment period, FDA received comments requesting that various devices be added to the list of devices that the agency was proposing be exempt from the requirement of premarket notification. The agency also received comments requesting that existing exemptions from the requirement of premarket notification for several devices, when made of certain materials, be expanded to include all devices within the classification, regardless of material composition. FDA is considering these comments and will address them in a future issue of the **Federal Register**.

Several comments requested that certain devices proposed for exemption from premarket notification also be exempted from the requirements of current good manufacturing practices (CGMP's) and records and reports. FDA has decided not to grant these additional exemptions at this time. Pursuant to 21 CFR 820.1(d), any person petitioning for an exemption from any device CGMP requirement is required to follow the procedures set forth in 21 CFR 10.30. Accordingly, the devices listed in this final rule as exempt from premarket notification continue to be subject to applicable CGMP requirements. FDA believes that compliance with CGMP's is necessary in order to ensure adequate protection of the public health

III. Conclusion

Several comments questioned the appropriateness of the proposed exemptions for a small number of the devices. In addition, FDA is reconsidering the appropriateness or scope of the proposed exemptions for several devices included in the proposed rule. Therefore, FDA is deferring action on the following 16 devices in order to review these comments and to reevaluate whether certain of the devices should be exempted from the requirement of premarket notification.

TABLE 1

CFR section	Device
862.2270 ..	Thin-layer chromatography system for clinical use.
862.2310 ..	Clinical sample concentrator.
862.2320 ..	Beta or gamma counter for clinical use.
862.2485 ..	Electrophoresis apparatus for clinical use.
862.2720 ..	Plasma oncometer for clinical use.
862.2800 ..	Refractometer for clinical use.
862.2920 ..	Plasma viscometer for clinical use.
864.2280 ..	Cultured animal and human cells.
866.5570 ..	Lactoferrin immunological test system.
868.5620 ..	Breathing mouthpiece.
868.5675 ..	Rebreathing device.
868.5700 ..	Nonpowered oxygen tent.
872.3740 ..	Retentive and splinting pin.
872.3810 ..	Root canal post.
872.6100 ..	Anesthetic warmer.
886.5850 ..	Sunglasses (nonprescription).

FDA will address these devices in a future issue of the **Federal Register.**

FDA received no adverse comments on 148 of the devices that it proposed be exempted from the requirement of premarket notification. For these 148 devices, FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Thus, FDA is finalizing the exemptions for these 148 devices from premarket notification procedures.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule reduces a regulatory burden by exempting manufacturers of devices subject to the final rule from the requirements of premarket notification, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Parts 868, 870, 872, 874, 876, 878, 880, 882, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 864.5350 is amended by revising paragraph (b) to read as follows:

§ 864.5350 Microsedimentation centrifuge.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

3. Section 864.7660 is amended by revising paragraph (b) to read as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 864.7675 is amended by revising paragraph (b) to read as follows:

§ 864.7675 Leukocyte peroxidase test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 864.7900 is amended by revising paragraph (b) to read as follows:

§ 864.7900 Thromboplastin generation test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 864.8500 is amended by revising paragraph (b) to read as follows:

§ 864.8500 Lymphocyte separation medium.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

7. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

8. Section 866.5170 is amended by revising paragraph (b) to read as follows:

§ 866.5170 Breast milk immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

9. Section 866.5220 is amended by revising paragraph (b) to read as follows:

§ 866.5220 Cohn fraction II immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

10. Section 866.5230 is amended by revising paragraph (b) to read as follows:

§ 866.5230 Colostrum immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 866.5360 is amended by revising paragraph (b) to read as follows:

§ 866.5360 Cohn fraction IV immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 866.5370 is amended by revising paragraph (b) to read as follows:

§ 866.5370 Cohn fraction V immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 866.5540 is amended by revising paragraph (b) to read as follows:

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 866.5700 is amended by revising paragraph (b) to read as follows:

§ 866.5700 Whole human plasma or serum immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 868—ANESTHESIOLOGY DEVICES

15. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

16. Section 868.5340 is amended by revising paragraph (b) to read as follows:

§ 868.5340 Nasal oxygen cannula.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.5350 is amended by revising paragraph (b) to read as follows:

§ 868.5350 Nasal oxygen catheter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 870—CARDIOVASCULAR DEVICES

18. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

19. Section 870.1875 is amended by revising paragraph (a)(2) to read as follows:

§ 870.1875 Stethoscope.

(a) * * *

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

PART 872—DENTAL DEVICES

20. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

21. Section 872.1500 is amended by revising paragraph (b) to read as follows:

§ 872.1500 Gingival fluid measurer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 872.1820 is amended by revising paragraph (b) to read as follows:

§ 872.1820 Dental X-ray exposure alignment device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

23. Section 872.3100 is amended by revising paragraph (b) to read as follows:

§ 872.3100 Dental amalgamator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

24. Section 872.3130 is amended by revising paragraph (b) to read as follows:

§ 872.3130 Preformed anchor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

25. Section 872.3165 is amended by revising paragraph (b) to read as follows:

§ 872.3165 Precision attachment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

26. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

27. Section 872.3285 is amended by revising paragraph (b) to read as follows:

§ 872.3285 Preformed clasp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

28. Section 872.3330 is amended by revising paragraph (b) to read as follows:

§ 872.3330 Preformed crown.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

29. Section 872.3350 is amended by revising paragraph (b) to read as follows:

§ 872.3350 Gold or stainless steel cusp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

30. Section 872.3360 is amended by revising paragraph (b) to read as follows:

§ 872.3360 Preformed cusp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

31. Section 872.3410 is amended by revising paragraph (b) to read as follows:

§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

32. Section 872.3450 is amended by revising paragraph (b) to read as follows:

§ 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

33. Section 872.3490 is amended by revising paragraph (b) to read as follows:

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

34. Section 872.3520 is amended by revising paragraph (b) to read as follows:

§ 872.3520 OTC denture cleanser.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

35. Section 872.3530 is amended by revising paragraph (b) to read as follows:

§ 872.3530 Mechanical denture cleaner.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

36. Section 872.3580 is amended by revising paragraph (b) to read as follows:

§ 872.3580 Preformed gold denture tooth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

37. Section 872.3670 is amended by revising paragraph (b) to read as follows:

§ 872.3670 Resin impression tray material.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

38. Section 872.3900 is amended by revising paragraph (b) to read as follows:

§ 872.3900 Posterior artificial tooth with a metal insert.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

39. Section 872.3910 is amended by revising paragraph (b) to read as follows:

§ 872.3910 Backing and facing for an artificial tooth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

40. Section 872.4130 is amended by revising paragraph (b) to read as follows:

§ 872.4130 Intraoral dental drill.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

41. Section 872.4535 is amended by revising paragraph (b) to read as follows:

§ 872.4535 Dental diamond instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

42. Section 872.4620 is amended by revising paragraph (b) to read as follows:

§ 872.4620 Fiber optic dental light.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

43. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

44. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

45. Section 872.5525 is amended by revising paragraph (b) to read as follows:

§ 872.5525 Preformed tooth positioner.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

46. Section 872.5550 is amended by revising paragraph (b)(1) to read as follows:

§ 872.5550 Teething ring.

* * * * *

(b)(1) *Classification.* Class I if the teething ring does not contain a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

47. Section 872.6030 is amended by revising paragraph (b) to read as follows:

§ 872.6030 Oral cavity abrasive polishing agent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

48. Section 872.6140 is amended by revising paragraph (b) to read as follows:

§ 872.6140 Articulation paper.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

49. Section 872.6250 is amended by revising paragraph (b) to read as follows:

§ 872.6250 Dental chair and accessories.

* * * * *

(b) *Classification.* Class I. The dental chair without the operative unit device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

50. Section 872.6300 is amended by revising paragraph (b) to read as follows:

§ 872.6300 Rubber dam and accessories.

* * * * *

(b) *Classification.* Class I. The accessories to the device, i.e., rubber dam clamp, rubber dam frame and forceps for a rubber dam clamp, are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

51. Section 872.6475 is amended by revising paragraph (b) to read as follows:

§ 872.6475 Heat source for bleaching teeth.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

52. Section 872.6510 is amended by revising paragraph (b) to read as follows:

§ 872.6510 Oral irrigation unit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

53. Section 872.6640 is amended by revising paragraph (b) to read as follows:

§ 872.6640 Dental operative unit and accessories.

* * * * *

(b) *Classification.* Class I. The accessories tray to the dental operative unit is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

54. Section 872.6865 is amended by revising paragraph (b) to read as follows:

§ 872.6865 Powered toothbrush.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

55. Section 872.6890 is amended by revising paragraph (b) to read as follows:

§ 872.6890 Intraoral dental wax.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 874—EAR, NOSE, AND THROAT DEVICES

56. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

57. Section 874.3375 is amended by revising paragraph (b) to read as follows:

§ 874.3375 Battery-powered artificial larynx.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

58. Section 874.4750 is amended by revising paragraph (b) to read as follows:

§ 874.4750 Laryngostroboscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

59. Section 874.5220 is amended by revising paragraph (b) to read as follows:

§ 874.5220 Ear, nose, and throat drug administration device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

60. Section 874.5800 is amended by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

61. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

62. Section 876.5970 is amended by revising paragraph (b) to read as follows:

§ 876.5970 Hernia support.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

63. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

64. Section 878.1800 is amended by revising paragraph (b) to read as follows:

§ 878.1800 Speculum and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

65. Section 878.3750 is amended by revising paragraph (b) to read as follows:

§ 878.3750 External prosthesis adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

66. Section 878.3800 is amended by revising paragraph (b) to read as follows:

§ 878.3800 External aesthetic restoration prosthesis.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

67. Section 878.3900 is amended by revising paragraph (b) to read as follows:

§ 878.3900 Inflatable extremity splint.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

68. Section 878.4100 is amended by revising paragraph (b) to read as follows:

§ 878.4100 Organ bag.

* * * * *

(b) *Classification.* Class I. The intestinal organ bag device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

69. Section 878.4380 is amended by revising paragraph (b) to read as follows:

§ 878.4380 Drape adhesive.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

70. Section 878.4440 is amended by revising paragraph (b) to read as follows:

§ 878.4440 Eye pad.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

71. Section 878.4470 is amended by revising paragraph (b) to read as follows:

§ 878.4470 Surgeon's gloving cream.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

72. Section 878.4635 is amended by revising paragraph (b) to read as follows:

§ 878.4635 Ultraviolet lamp for tanning.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

73. Section 878.4660 is amended by revising paragraph (b) to read as follows:

§ 878.4660 Skin marker.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

74. Section 878.4700 is amended by revising paragraph (b) to read as follows:

§ 878.4700 Surgical microscope and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 878.4730 is amended by revising paragraph (b) to read as follows

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

76. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 878.4930 is amended by revising paragraph (b) to read as follows

§ 878.4930 Suture retention device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 878.4950 is amended by revising paragraph (b) to read as follows:

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

79. Section 878.5900 is amended by revising paragraph (b) to read as follows:

§ 878.5900 Nonpneumatic tourniquet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

80. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

81. Section 880.2400 is amended by revising paragraph (b) to read as follows:

§ 880.2400 Bed-patient monitor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 880.2720 is amended by revising paragraph (b)(1) to read as follows:

§ 880.2720 Patient scale.

* * * * *

(b) *Classification.* (1) Class I for a mechanical or battery powered patient scale. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

* * * * *

83. Section 880.5180 is amended by revising paragraph (b) to read as follows:

§ 880.5180 Burn sheet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 880.5210 is amended by revising paragraph (b) to read as follows:

§ 880.5210 Intravascular catheter securement device.

* * * * *

(b) *Classification.* Classs I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

85. Section 880.5240 is amended by revising paragraph (b) to read as follows:

§ 880.5240 Medical adhesive tape and adhesive bandage.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

86. Section 880.5630 is amended by revising paragraph (b) to read as follows:

§ 880.5630 Nipple shield.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

87. Section 880.5740 is amended by revising paragraph (b) to read as follows:

§ 880.5740 Suction snakebite kit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 880.5780 is amended by revising paragraph (b)(2) to read as follows:

§ 880.5780 Medical support stocking.

* * * * *

(b) * * *

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

89. Section 880.5950 is amended by revising paragraph (b) to read as follows:

§ 880.5950 Umbilical occlusion device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

90. Section 880.6060 is amended by revising paragraph (b) to read as follows:

§ 880.6060 Medical disposable bedding.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

91. Section 880.6150 is amended by revising paragraph (b) to read as follows:

§ 880.6150 Ultrasonic cleaner for medical instruments.

* * * * *

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

92. Section 880.6190 is amended by revising paragraph (b) to read as follows:

§ 880.6190 Mattress cover for medical purposes.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

93. Section 880.6900 is amended by revising paragraph (b) to read as follows:

§ 880.6900 Hand-carried stretcher.

* * * * *

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

PART 882—NEUROLOGICAL DEVICES

94. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

95. Section 882.1430 is amended by revising paragraph (b) to read as follows:

§ 882.1430 Electroencephalograph test signal generator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

96. Section 882.1700 is amended by revising paragraph (b) to read as follows:

§ 882.1700 Percussor.

* * * * *

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

97. Section 882.1925 is amended by revising paragraph (b) to read as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

98. Section 882.4030 is amended by revising paragraph (b) to read as follows:

§ 882.4030 Skull plate anvil.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

99. Section 882.4125 is amended by revising paragraph (b) to read as follows:

§ 882.4125 Neurosurgical chair.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

100. Section 882.4190 is amended by revising paragraph (b) to read as follows:

§ 882.4190 Clip forming/cutting instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 882.4200 is amended by revising paragraph (b) to read as follows:

§ 882.4200 Clip removal instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 882.4215 is amended by revising paragraph (b) to read as follows:

§ 882.4215 Clip rack.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 882.4440 is amended by revising paragraph (b) to read as follows:

§ 882.4440 Neurosurgical headrest.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 882.4500 is amended by revising paragraph (b) to read as follows:

§ 882.4500 Cranioplasty material forming instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 882.4525 is amended by revising paragraph (b) to read as follows:

§ 882.4525 Microsurgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 882.4535 is amended by revising paragraph (b) to read as follows:

§ 882.4535 Nonpowered neurosurgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

107. Section 882.4600 is amended by revising paragraph (b) to read as follows:

§ 882.4600 Leukotome.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

108. Section 882.4900 is amended by revising paragraph (b) to read as follows:

§ 882.4900 Skullplate screwdriver.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

109. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

110. Section 886.1040 is amended by revising paragraph (b) to read as follows:

§ 886.1040 Ocular esthesiometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

111. Section 886.1050 is amended by revising paragraph (b) to read as follows:

§ 886.1050 Adaptometer (biophotometer).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

112. Section 886.1070 is amended by revising paragraph (b) to read as follows:

§ 886.1070 Anomaloscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

113. Section 886.1090 is amended by revising paragraph (b) to read as follows:

§ 886.1090 Haidlinger brush.

* * * * *

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

114. Section 886.1140 is amended by revising paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

115. Section 886.1160 is amended by revising paragraph (b) to read as follows:

§ 886.1160 Color vision plate illuminator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

116. Section 886.1250 is amended by revising paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

* * * * *

(b) *Classification.* Class I for the battery powered device. The battery powered device is exempt from premarket notification procedures in subpart E of part 807 of this chapter. Class II for the AC-powered device.

117. Section 886.1290 is amended by revising paragraph (b) to read as follows:

§ 886.1290 Fixation device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

118. Section 886.1340 is amended by revising paragraph (b) to read as follows:

§ 886.1340 Haploscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

119. Section 886.1350 is amended by revising paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

* * * * *

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

120. Section 886.1425 is amended by revising paragraph (b) to read as follows:

§ 886.1425 Lens measuring instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

121. Section 886.1430 is amended by revising paragraph (b) to read as follows:

§ 886.1430 Ophthalmic contact lens radius measuring device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

122. Section 886.1435 is amended by revising paragraph (b) to read as follows:

§ 886.1435 Maxwell spot.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

123. Section 886.1450 is amended by revising paragraph (b) to read as follows:

§ 886.1450 Corneal radius measuring device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device does not include computer software in the unit or topographers.

124. Section 886.1660 is amended by revising paragraph (b) to read as follows:

§ 886.1660 Gonioscopic prism.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

125. Section 886.1680 is amended by revising paragraph (b) to read as follows:

§ 886.1680 Ophthalmic projector.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

126. Section 886.1690 is amended by revising paragraph (b) to read as follows:

§ 886.1690 Pupillograph.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

127. Section 886.1700 is amended by revising paragraph (b) to read as follows:

§ 886.1700 Pupillometer.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

128. Section 886.1810 is amended by revising paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

129. Section 886.1860 is amended by revising paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

130. Section 886.1870 is amended by revising paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

131. Section 886.1910 is amended by revising paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

132. Section 886.1945 is amended by revising paragraph (b) to read as follows

§ 886.1945 Transilluminator.

* * * * *

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

133. Section 886.4250 is amended by revising paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

* * * * *

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered Class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

134. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device meets the ANSI standard on optic radiation limits.

135. Section 886.4360 is amended by revising paragraph (b) to read as follows:

§ 886.4360 Ocular surgery irrigation device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

136. Section 886.4570 is amended by revising paragraph (b) to read as follows:

§ 886.4570 Ophthalmic surgical marker.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter.

137. Section 886.4750 is amended by revising paragraph (b) to read as follows:

§ 886.4750 Ophthalmic eye shield.

* * * * *

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

138. Section 886.4855 is amended by revising paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

139. Section 886.5820 is amended by revising paragraph (b) to read as follows:

§ 886.5820 Closed-circuit television reading system.

* * * * *

(b) *Classification.* Class I. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

140. Section 886.5840 is amended by revising paragraph (b) to read as follows:

§ 886.5840 Magnifying spectacles.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

141. Section 886.5842 is amended by revising paragraph (b) to read as follows:

§ 886.5842 Spectacle frame.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

142. Section 886.5844 is amended by revising paragraph (b) to read as follows:

§ 886.5844 Prescription spectacle lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

143. Section 886.5900 is amended by revising paragraph (b) to read as follows:

§ 886.5900 Electronic vision aid.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

144. Section 886.5915 is amended by revising paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 888—ORTHOPEDIC DEVICES

145. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

146. Section 888.4200 is amended by revising paragraph (b) to read as follows:

§ 888.4200 Cement dispenser.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

147. Section 888.4210 is amended by revising paragraph (b) to read as follows:

§ 888.4210 Cement mixer for clinical use.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

148. Section 888.4230 is amended by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

149. Section 888.4540 is amended by revising paragraph (b) to read as follows:

§ 888.4540 Orthopedic manual surgical instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

150. Section 888.5940 is amended by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 890—PHYSICAL MEDICINE DEVICES

151. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

152. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

153. Section 890.3100 is amended by revising paragraph (b) to read as follows:

§ 890.3100 Mechanical chair.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

154. Section 890.3750 is amended by revising paragraph (b) to read as follows:

§ 890.3750 Mechanical table.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

155. Section 890.3920 is amended by revising paragraph (b) to read as follows:

§ 890.3920 Wheelchair component.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

156. Section 890.3940 is amended by revising paragraph (b) to read as follows:

§ 890.3940 Wheelchair platform scale.

* * * * *

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

157. Section 890.5765 is amended by revising paragraph (b) to read as follows:

§ 890.5765 Pressure-applying device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 892—RADIOLOGY DEVICES

158. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

159. Section 892.1130 is amended by revising paragraph (b) to read as follows:

§ 892.1130 Nuclear whole body counter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

160. Section 892.1350 is amended by revising paragraph (b) to read as follows:

§ 892.1350 Nuclear scanning bed.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is labeled with weight limit, is used with planar scanning only, and is not for diagnostic X-ray use.

161. Section 892.1640 is amended by revising paragraph (b) to read as follows:

§ 892.1640 Radiographic film marking system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

162. Section 892.5740 is amended by revising paragraph (b) to read as follows:

§ 892.5740 Radionuclide teletherapy source.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: November 30, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94–30025 Filed 12–2–94; 12:01 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 91

[OJP No. 1011]

RIN 1121–AA25

Violent Offender Incarceration and Truth in Sentencing Incentive Grant Program

AGENCY: Department of Justice, Office of Justice Programs (OJP).

ACTION: Interim final rule.

SUMMARY: This interim rule implements and requests comments regarding the Violent Offender Incarceration and Truth in Sentencing Incentive Grant Program, Subtitle A of Title II of the Violent Crime Control and Law Enforcement Act of 1994.

The Violent Offender Incarceration and Truth in Sentencing Grant Program will provide grants to states, and states organized in multi-state compacts, for assistance to correctional systems. These regulations are being issued in accordance with the mandate in Subtitle A of Title II that rules and regulations regarding the uses of grant funds under this program be issued. While this rule discusses the implementation of the overall Subtitle A program, fiscal year 1995 funds have only been appropriated for the construction-related costs of correctional boot camps.

DATES: Interim rule effective on December 7, 1994; comments must be received March 7, 1995.

ADDRESSES: Comments may be sent to Marlene Beckman at the Office of Justice Programs, 633 Indiana Avenue, 13th Floor, NW, Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: The Department of Justice Response Center at 1–800–421–6770 or (202) 307–1480.

SUPPLEMENTARY INFORMATION: Federal funding is authorized under Subtitle A of Title II of the Violent Crime Control and Law Enforcement Act of 1994 (Subtitle A), Public Law 103–322, for grants to states, and states organized in multi-state compacts, for assistance to adult and juvenile correctional systems. The program recognizes that states and local jurisdictions have experienced substantial increases in jail, prison and juvenile confinement populations in recent years, resulting in escalating costs and serious difficulties in managing overcapacity correctional populations. Because of these constraints, correctional systems have often been unable to implement new programs, develop alternative confinement strategies, or open new facilities. This program seeks to provide funds to address the immediate needs of correctional facilities and programs.

In particular, the program emphasizes the need to make available both conventional jail and prison space for the confinement of violent offenders and to ensure that violent offenders remain incarcerated for substantial periods of time through the implementation of truth in sentencing laws. Accordingly, Subtitle A directs the Attorney General to award grants to construct, develop, expand, modify, operate, or improve correctional facilities, including boot camp facilities and other alternative correctional facilities that will free secure prison space for the confinement of violent offenders.

Fifty percent of the total amount of funds appropriated each year will be allocated for Truth in Sentencing Incentive Grants and the other 50 percent will be allocated for Violent Offender Incarceration Grants, 85 percent of which is to be distributed by specified formula with the remaining 15 percent available for discretionary grant awards.

The formula amount available to carry out the grant programs for any fiscal year will be allocated to each eligible state based on Part 1 violent crime data reported to the Federal Bureau of Investigation for use in the Uniform Crime Reports (UCR). If such data is unavailable, applicants may also utilize figures as reported in publications by the Bureau of Justice Statistics (BJS). (See, e.g., "Census of State and Local Correctional Facilities, 1990.")

The statute contemplates the availability of $7.9 billion in funding over six years, beginning with $175 million authorized in fiscal year 1995. It is important to note, however, that Congress appropriated only $24.5 million for Subtitle A programs for fiscal year 1995. Moreover, the Appropriations Act limits these funds to