comments, and the Secretary's responses to them, are summarized below. No changes were made to the priorities as a result of the comments.

Comment: One commenter suggested that the priority for automated data exchange between the Social Security Disability Determination Units and rehabilitation agencies and facilities should include data from private practitioners as well as procedures for timely correction of errors that might be made in determinations.

Response: No change has been made. The Secretary agrees that these are worthwhile objectives, but does not want to broaden the scope of this project by requiring grantees to undertake these activities.

Comment: One commenter suggested that the priority for rural rehabilitation should include the development of a telecommunications system for rural service delivery.

Response: No change has been made. The priority as stated does not preclude an applicant from using this approach, and this is certainly one technique to achieve the objectives of the priority. However, the Secretary does not intend to require that all applicants include telecommunications systems in their project proposals.

Comment: One commenter urged that augmentative communication devices should be among those considered in the development of technology service delivery models in the South Carolina and Connecticut Rehabilitation Engineering Centers.

Response: No change has been made. The priority as stated includes all types of technological devices and services that are used by individuals with disabilities.

Comment: One commenter suggested that the priority for managing behavioral problems in individuals with developmental disabilities should focus on persons residing in institutional settings and should focus on emotional disorders as well as behavioral problems.

Response: No change has been made. The Secretary agrees that individuals who reside in institutions should benefit from the interventions developed. However, the purpose of this priority is to develop techniques for dealing with disruptive behavior in integrated settings of individuals with developmental disabilities who reside in the community. Further, the focus of this priority is on treating individuals with developmental disabilities who exhibit problem behaviors. Emotional disorders may or may not be present and may or may not be diagnosed in these individuals, but it is the remediation of disruptive behavior that is the purpose of this priority.

Comment: Several commenters objected to the specification that the two Engineering Centers be located in Connecticut and South Carolina, arguing that NIDRR may not be able to fund the best programs under these restrictions.

Response: No change has been made. The Secretary agrees that under these restrictions NIDRR may not be able to fund the best candidates for establishing two new Engineering Centers. However, the Rehabilitation Act Amendments of 1986 specifically require NIDRR to establish Rehabilitation Engineering Centers in these two States.

(Catalog of Federal Domestic Assistance No. 84.133, National Institute on Disability and Rehabilitation Research)

Dated: July 6, 1987.

William J. Bennett,

Secretary of Education.

[FR Doc. 87-18184 Filed 8-11-87; 8:45 am]

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federal register

Wednesday
August 12, 1987

Part V

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 1, 5, 7, et al.
Federal Acquisition Regulation; Final Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 5, 7, 13, 19, 22, 25, 28, 31, 32, 45, 52, and 53

[Federal Acquisition Circular 84-29]

Federal Acquisition Regulation

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: Federal Acquisition Circular (FAC) 84-29 amends the Federal Acquisition Regulation (FAR) with respect to the following: Public Announcement of Contract Awards; Economic Order Quantities; Small Business Size Standards; Regular Dealer—Specialty Advertising Product Dealer; Bid Guarantee, Optional Overseas; Contracts with Indian Tribal Governments, Correction of FAR 31.107; Reducing Customary Progress Payment Rates; Use of Government Property; Inventory Schedules, Preparing and Submitting Standard Form (SF) 1432; FAR Changes Clauses; Revision of Standard Form (SF) 1436, Settlement Proposal (Total Cost Basis); and Editorial Corrections.

EFFECTIVE DATE: August 24, 1987.

FOR FURTHER INFORMATION CONTACT: Margaret A. Willis, FAR Secretariat, Room 4041, GS Building, Washington, DC 20405, Telephone (202) 523-4755.

SUPPLEMENTARY INFORMATION:

A. Paperwork Reduction Act

FAC 84-29, Items I, III, V, VI, VII, VIII, IX, X, XI, and XII. The Paperwork Reduction Act (Pub. L. 96-511) does not apply because these final rules do not impose any additional reporting or recordkeeping requirements on the public which require the approval of OMB under 44 U.S.C. 3501, et seq.

FAC 84-29, Item II. The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501, et seq., and have been assigned OMB control number 9000-0082 (see FAR 1.105).

FAC 84-29, Item IV. Coverage on the Paperwork Reduction Act (Pub. L. 96-511) has been handled by the Department of Labor and approved by OMB as required by 44 U.S.C. 3501, et seq., and has been assigned OMB control number 1215-0157 (see FAR 1.105).

B. Regulatory Flexibility Act

FAC 84-29, Item I, III, V, VIII, IX, XI, and XII. Analyses of these revisions indicate that they are not "significant revisions" as defined in FAR 1.501-1; i.e., they do not alter the substantive meaning of any coverage in the FAR having a significant cost or administrative impact on contractors or offerors, or a significant effect beyond the internal operating procedures of the issuing agencies. Accordingly, and consistent with section 1212 of Pub. L. 98-525 and section 302 of Pub. L. 98-577 pertaining to publication of proposed regulations (as implemented in FAR Subpart 1.5, Agency and Public Participation), solicitation of agency and public views on these revisions is not required. Since such solicitation is not required, the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) does not apply.

FAC 84-29, Item II. It is certified that the revised FAR coverage on planning for the purchase of supplies in economic quantities will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) because it does not impose additional mandatory reporting requirements or add new contractual requirements on small businesses. Responses to the prescribed solicitation notice are entirely voluntary and the type of information requested should normally be readily available in small businesses.

FAC 84-29, Item IV. The Department of Labor (DOL) performed a regulatory flexibility analysis at the time DOL issued the final rule in their regulation which this FAR final rule implements. Accordingly, a new analysis is not required for this rule.

FAC 84-29, Item VI. It is certified that this revision to FAR 31.107 does not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) because it merely adds language that was erroneously omitted when the FAR was originally published. FAR Subpart 31.6, which is referenced in FAR 31.107, already makes reference to federally recognized Indian tribal governments. No change in coverage or meaning is intended or made.

FAC 84-29, Item VII. Since the publication of a proposed FAR rule dealing with customary progress payment rates on September 2, 1986 (51 FR 31194), section 9105 of the fiscal year 1987 Department of Defense Appropriations Act (Title IX, Pub. L. 99-500) directed a reduction in progress payment rates of at least 5 percent for DOD contracts. As a consequence, the DOD FAR Supplement has been revised to establish customary progress payment rates for DOD contracts of 75 percent for large business and 80 percent for small businesses.

The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council have decided to implement the originally proposed customary progress payment rates of 80 percent for large businesses and 85 percent for small business in the FAR for application to agencies other that DOD. These are the historical rates that were in effect before the prevailing interest rates of the early 1980's prompted the Government to increase progress payment rates to their present levels of 90 percent for large businesses and 95 percent for small businesses. They are also the rates recommended by a number of Government studies (e.g., Grace Commission and DOD's Defense Financial and Investment Review).

As the vast majority of progress payments made, perhaps as large a percentage as 90 percent, occur under DOD contracts, an insubstantial number of small entities will be affected by the FAR rule. Therefore, it is certified that this revision will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.).

FAC 84-29, Item X. A notice of request for public comments was published in the **Federal Register** on May 23, 1985 (50 FR 21313). Because of the comments received from industry, a proposed rule was published on May 2, 1986 (51 FR 16462). A summary of the initial Regulatory Flexibility Act Analysis was published on May 2, 1986. A final Regulatory Flexibility Analysis has been performed and is on file in the office of the FAR Secretariat.

C. Public Comments

FAC 84-29, Item II. Federal Acquisition Circular (FAC) 84-11, published in the **Federal Register** on August 30, 1985, included an interim rule on planning for the purchase of supplies in economic quantities. As a result of public comments received, that coverage was revised and is hereby published as a final rule. However, FAR sections 14.212 and 15.415 are being finalized without change.

FAC 84-29, Item VII. A notice of the proposed rule was published in the **Federal Register** on September 2, 1986 (51 FR 31194). The Defense Acquisition Regulatory Council and the Civilian

Agency Acquisition Council have considered the public comments solicited. Three of 22 respondents stated that an 85 percent progress payment rate as versus the current 95 percent rate would place too much burden on small business contractors. The Councils believe that reductions in customary progress payment rates for both large and small businesses are in keeping with improvements in the economic environment. For example, the prime interest rate is now in the neighborhood of 7.5 percent as compared to 19 percent when the progress payment rates were raised from 80 percent for large businesses and 85 percent for small businesses.

It is recognized that small businesses have a higher financing burden as described by some of the respondents. However, the higher burdens are the reasons why some of the rules are more liberal for small businesses. Differences in rules include: higher customary progress payment rate (e.g., 85 percent versus 80 percent), lower threshold for incorporating progress payment provisions into contracts, and paying almost all costs on an incurred basis rather than to delay payments until cash disbursements have been made by the contractor. Based on the comments received, the Councils are not persuaded that arguments emphasizing higher small business burdens overcome the significant interest rate decreases which have occurred and the more liberal rules for small businesses already in place.

Consequently, the proposed rule is being adopted as a final rule.

List of Subjects in 48 CFR Parts 1, 5, 7, 13, 19, 22, 25, 28, 31, 32, 45, 52, and 53

Government procurement.

Date: August 6, 1987.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

Federal Acquisition Circular

[Number 84-29]

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 84-29 is effective August 24, 1987.

Eleanor R. Spector,

Deputy Assistant Secretary of Defense for Procurement.

August 6, 1987.

Terence C. Golden,

Administrator, GSA.

July 30, 1987.

S.J. Evans,

Assistant Administrator for Procurement, NASA.

August 6, 1987.

Federal Acquisition (FAC) 84-29 amends the Federal Acquisition Regulation (FAR) as specified below.

Item I—Public Announcement of Contract Awards

FAR 5.303 is revised to allow agencies to announce awards at a minimum dollar threshold other than $3 million if they so desire. This was done to recognize the fact that the same threshold was not suitable for all agencies and to eliminate the need for FAR changes or deviations to accommodate the different needs of disparate agencies.

Item II—Economic Order Quantities

FAR Subpart 7.2 and FAR 52.207-4 which were incorporated in FAC 84-11 as interim rules (see Item II of FAC 84-11 published in the **Federal Register** on August 30, 1985 [50 FR 35474]) are hereby revised and incorporated as final rules to prescribe policies, procedures, and a contract provision for gathering and using information from offerors to assist the Government in planning the most advantageous quantities in which supplies should be purchased. FAR sections 14.212 and 15.415 are adopted as final rules without change. Under the final coverage, offerors are invited to state an opinion on whether the quantity of supplies proposed to be acquired is economically advantageous to the Government and, if applicable, to recommend a more advantageous quantity, including a quoted unit and total price. FAR 52.207-4 is modified to revise the definition of "economic purchase, quantity" in paragraph (b) of the solicitation provision. A revision to FAR 13.107(d) is added in the final rule to extend the requirements of the interim rule to small purchases. Also, FAR 7.203 is revised to (1) make mandatory, rather than optional, the requirement for civilian agencies to include the provision at FAR 52.207-4 in solicitations for supplies, and (2) provide a number of exemptions where the provision need not be included in solicitations. This FAR amendment implements section 1233 of Pub. L. 98-525 and section 205 of Pub. L. 98-577.

Item III—Small Business Size Standards

FAR 19.102 is revised in the table of industry size standards to reflect corrections made by the Small Business Administration in FR Doc. 87-12906 published in the **Federal Register** issue of June 8, 1987 (52 FR 21497).

Item IV—Regular Dealer—Specialty Advertising Product Dealer

FAR 22.606-2(b) is revised to comply with the Department of Labor's amendment to the Walsh-Healy Public Contracts Act regulations to provide an alternative definition for a regular dealer in specialty advertising products.

Item V—Bid Guarantee, Optional Overseas

FAR 28.101-1(c) is revised to permit a waiver for bid guarantees for construction work to be performed overseas.

Item VI—Contracts With Indian Tribal Governments

FAR 31.107 is revised to add an erroneously omitted reference to "federally recognized Indian tribal governments" in the applicability language for FAR Subpart 31.6—Contracts With State, Local, and Federally Recognized Indian Tribal Governments.

Item VII—Reducing Customary Progress Payment Rates

FAR Part 32 revised to accomplish the following: (1) Lower the customary progress payment rate for large businesses from 90% to 80% and for small businesses from 95% to 85%, (2) incorporate the progress payment limitations on undefinitized contract actions that had been established under the Defense Procurement Improvement Act of 1986, and (3) provide guidance for situations where more than one progress payment rate is being used

Item VIII—Use of Government Property

FR 45.509-2(b) is revised by (a) establishing a specified dollar level, i.e., an acquisition cost of $5,000 or more, as the threshold for application of the requirements in FAR 45.509-2(b) (1) through (b)(4), and (b) changing the term "package plants and standby lines" to "plants and equipment retained for mobilization."

Item IX—Inventory Schedules, Preparing and Submitting Standard Form (SF) 1432

FAR 45.606-5(e)(4)(ii) is revised to clarify the descriptive information to be included on the SF 1432 when a contractor reports excess special tooling

and special test equipment for disposal action. In order to permit the Government to determine the appropriate disposition and to maximize the reutilitzation potential, the function performed by, and the end-item application of, the special tooling or the special test equipment must be included on the inventory schedule. An editorial change to 45.606–5(e)(4)(i) is also made.

Item X—FAR Changes Clauses

FAR clauses 52.243–1, 52.243–2, 52.243–3, and 52.243–4 are amended to reinstate the pre-FAR requirement that the contractor must "assert its right to an adjustment" rather than "submit its proposal for adjustment" within 30 days from the receipt of a written order. While this action corrects an unintended policy change which occurred during drafting of the FAR, contractors should not construe this action as a relaxation of the FAR 43.204 requirement for prompt definitization of unpriced change orders.

Item XI—Settlement Proposal (Total Cost Basis), Revision of Standard Form (SF) 1436

FAR 53.249, Termination of contracts (SF's 1034 and 1435 through 1440), is amended in paragraph (a)(3) to allow for the correction of a typographical error on SF 1436. Pending the publication of a new edition of the form, currently dated October 1983, a pen and ink change to Item 7, Section II of the form is authorized and should read, "Total Costs (Items 1 thru 6)."

Item XII—Editorial Corrections

Therefore, 48 CFR Parts 1, 5, 7, 13, 19, 22, 25, 28, 31, 32, 45, 52, and 53 are amended as set forth below.

The interim rule (FAC 84–17) amending Part 25 and sections 52.225–8 and 52.225–9 which was published on May 6, 1986 (51 FR 16802), with a correction on June 10, 1986 (51 FR 20976), is hereby adopted as a final rule without change.

The interim rule (FAC 84–22) amending Part 25, which was published in the **Federal Register** on August 27, 1986 (51 FR 30618), with a correction published on March 23, 1987 (52 FR 8567), is hereby adopted as a final rule.

1. The authority citation for 48 CFR Parts 1, 5, 7, 13, 19, 22, 25, 28, 31, 32, 45, 52, and 53 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2473(c).

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

2. Section 1.105 is amended by adding, in numerical order, two FAR segments, each with a corresponding OMB Control Number to read as follows:

1.105 OMB approval under the Paperwork Reduction Act.

FAR segment	OMB control No.
* * * * *	
7.2	9000–0082
* * * * *	
22.606–2(b)	1215–0157
* * * * *	

PART 5—PUBLICIZING CONTRACT ACTIONS

3. Section 5.303 is amended by revising in paragraph (a) the first sentence to read as follows:

5.303 Announcement of contract awards.

(a) * * * Contracting officers shall make information available on awards over $3 million (unless another dollar amount is specified in agency acquisition regulations) in sufficient time for the agency concerned to announce it by Washington, DC time on the day of award. * * *

PART 7—ACQUISITION PLANNING

4. Section 7.203 is revised to read as follows:

7.203 Solicitation provision.

Contracting officers shall insert the provision at 52.207–4, Economic Purchase Quantity—Supplies, in solicitations for supplies. The provision need not be inserted if the solicitation is for a contract under the General Services Administration's multiple award schedule contract program, or if the contracting officer determines that (a) the Government already has the data, (b) the data is otherwise readily available, or (c) it is impracticable for the Government to vary its future requirements.

PART 13—SMALL PURCHASE AND OTHER SIMPLIFIED PROCEDURES

5. Section 13.107 is amended by adding paragraph (d) to read as follows:

13.107 Solicitation and evaluation of quotations.

* * * * *

(d) *Economic purchase quantities (supplies).* Contracting officers shall comply with the economic purchase quantity planning requirements for supplies in Subpart 7.2. If quotations are solicited in writing, contracting officers shall comply with 7.203 and 7.204. If quotations are solicited orally, contracting officers shall orally request the information covered by the provision at 52.207–4 in accordance with the instructions at 7.203 and then comply with 7.204.

PART 19—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

19.102 [Amended]

6. Section 19.102 is amended by removing the figure "$0.1" in Major Group 02 for SIC Code 0212–0291 and inserting in its place the figure "$0.5".

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

7. Section 22.606–2 is amended by revising paragraph (b) to read as follows:

22.606–2 Regular dealer.

* * * * *

(b) For certain specific products (lumber and timber products, machine tools, hay, grain, feed or straw, raw cotton, green coffee, petroleum, agricultural liming materials, tea, raw or unmanufactured cotton linters, certain uranium products, used automatic data processing equipment, and specialty advertising products), there are alternate qualifications for regular dealers in which the dealer need not physically maintain a stock. The requirements under the alternative qualifications are in 41 CFR 50–201.101(a)(2) and 50–201.604.

* * * * *

PART 28—BONDS AND INSURANCE

8. Section 28.101–1 is amended by adding paragraph (c) to read as follows:

28.101–1 Policy on use.

* * * * *

(c) The head of the contracting activity may waive the requirement for bid guarantees if it is determined that bid guarantees are not in the best interest of the Government in contracting for construction to be performed overseas.

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

9. Section 31.107 is amended by revising the section title and paragraph (a) to read as follows:

31.107 Contracts with State, local, and federally recognized Indian tribal governments.

(a) Subpart 31.6 provides principles and standards for determining costs

applicable to contracts with State, local, and federally recognized Indian tribal governments. They provide the basis for a uniform approach to the problem of determining costs and to promote efficiency and better relationships between State, local, and federally recognized Indian tribal governments, and Federal Government entities. They apply to all programs that involve contracts with State, local, and federally recognized Indian tribal governments, except contracts with—

* * * * *

31.205-44 [Amended]

10. Section 31.205-44 is amended in the first sentence of paragraph (i) by inserting a comma following the word "tuition".

PART 32—CONTRACT FINANCING

11. Section 32.001 is added to read as follows:

32.001 Definition.

"Contract action," as used in this part, means an action resulting in a contract, as defined in FAR Subpart 2.1, including contract modifications for additional supplies or services, but not including contract modifications that are within the scope and under the terms of the contract, such as contract modifications issued pursuant to the Changes clause, or funding and other administrative changes.

12. Section 32.102 is amended by revising paragraph (e)(2) to read as follows:

32.102 Description of contract financing methods.

* * * * *

(e) * * *

(2) This type of progress payment may be used as a payment method under agency procedures. Agency procedures must ensure that payments are commensurate with work accomplished, which meets the quality standards established under the contract. Furthermore, progress payments may not exceed 80 percent of the eligible costs of work accomplished on undefinitized contract actions.

13. Section 32.501-1 is amended by revising the first two sentences in paragraph (a) and by adding paragraph (d) to read as follows:

32.501-1 Customary progress payment rates.

(a) The customary progress payment rate is 80 percent, applicable to the total costs of performing the contract. The customary rate for contracts with small business concerns is 85 percent. * * *

* * * * *

(d) In accordance with the Defense Procurement Improvement Act of 1986 (Pub. L. 99-145) and, for civilian agencies, as a matter of policy, progress payments are limited to 80 percent on work accomplished under undefinitized contract actions. A higher rate is not authorized under unusual progress payments or flexible progress payments for the undefinitized actions.

14. Section 32.502-4 is amended by adding paragraph (d) to read as follows:

32.502-4 Contract clauses.

* * * * *

(d) If the nature of the contract necessitates separate progress payment rates for portions of work that are clearly severable and accounting segregation would be maintained (e.g., annual production requirements), the application of separate progress payment rates shall be fully described in a supplementary special provision within the contract. Separate progress payment requests and subsequent invoices shall be submitted by the contractor for the severable portions of work in order to maintain accounting integrity.

15. Section 32.503-6 is amended by revising the following entries in Section II of paragraph (g)(4) to read as follows:

32.503-6 Suspension or reduction of payments.

(g) * * *

(4) * * *

Section II:

* * * * *

Progress payment rate	×80%
Alternate amount to be used	$599,760

* * * * *

16. Section 32.503-8 is amended by removing in the sixth sentence the figure "86.1" and inserting in its place the figure "76.5" and by revising the following entries in the sixth sentence to read as follows:

32.503-8 Liquidation rates—ordinary method.

* * * * *

Result × progress payment rate (4.33 × 80%)	Percent 3.46
Result subtracted from progress payment rate (80%–3.46%)	76.54

17. Section 32.503-10 is amended by revising paragraphs (b)(3)(i), (b)(3)(ii), and (b)(3)(iii) to read as follows:

32.503-10 Establishing alternate liquidation rates.

* * * * *

(b) * * *

(3) * * *

(i) If the progress payment rate is 80 percent, the minimum liquidation rate should be 72.7 percent, computed as follows:

$$\frac{(\$1{,}000{,}000 \times 80\%)}{\$1{,}100{,}000} = 72.7\%$$

(ii) If the progress payment rate is 85 percent, the minimum liquidation rate should be 77.3 percent, computed as follows:

$$\frac{(\$1{,}000{,}000 \times 85\%)}{\$1{,}100{,}000} = 77.3\%$$

(iii) If the contract is subject to CAS limitation on G&A eligible for progress payments (see 32.503-7), an adjusted alternate liquidation rate shall be established by subtracting the estimated G&A not eligible for progress payments from the total estimated contract costs. For example, if the price is $1,100,000, costs are $1,000,000, and unbilled G&A is $47,600, the liquidation rate should be 69.3 percent, computed as follows:

$$\frac{(\$1{,}000{,}000 - \$47{,}600)}{\$1{,}100{,}000} \times 80\% = 69.3\%$$

PART 45—GOVERNMENT PROPERTY

18. Section 45.509–2 is amended by revising paragraphs (b) and (b)(1) to read as follows:

45.509–2 Use of Government property.

* * * * *

(b) With respect to plant equipment with an acquisition value of $5,000 or more, the procedures, as a minimum, shall—

(1) Establish a minimum level of use below which an analysis of need shall be made and retention justified, except for inactive plants and equipment retained for mobilization (the use level may be established for individual items or families of items, depending upon circumstances of use);

* * * * *

19. Section 45.606–5 is amended by revising paragraphs (e)(4)(i) and (e)(4)(ii) to read as follows:

45.606–5 Instructions for preparing and submitting schedules of contractor inventory.

* * * * *

(e) * * *

(4) * * *

(i) *Classification.* Use of a new form for each general classification of special tooling and special test equipment.

(ii) *Description.* Furnish a description which will enable the plant clearance officer or screener to determine the appropriate disposition, including the potential for reutilization. Include tool nomenclature, tool number, related product part number, and function which the tool performs. Designate special tooling usable for maintenance programs by placing the letter "M" in the left-hand column, "For Use of Contracting Agency Only." Provide the end-item application and a brief description of the test function for each unit of special test equipment.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

20. Section 52.207–4 is amended by removing in the title of the provision the date "(JUL 1985)" and inserting in its place the date "(AUG 1987)" and by revising the third sentence in paragraph (b) of the provision to read as follows:

52.207–4 Economic Purchase Quantity—Supplies.

* * * * *

(b) * * * An economic purchase quantity is that quantity at which a significant price break occurs. * * *

52.223–3 [Amended]

21. Section 52.223–3 is amended by inserting a colon in the introductory text following the word "clause" and removing the remainder of the sentence; removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(AUG 1987)"; removing in the first sentence of paragraphs (a) and (b) of the clause the reference "313A" and inserting in each place the reference "313B"; removing in paragraph (e)(5)(ii) of the clause the reference "52.227–18" and inserting in its place the reference "52.227–14"; and removing the derivation line following "(End of clause)".

22. Section 52.232–5 is amended by removing in the title of the clause the date "(MAY 1986)" and inserting in its place the date "(AUG 1987)"; by revising the first sentence in paragraph (b) of the clause; and by adding paragraph (g) to read as follows:

52.232–5 Payments under fixed-price construction contracts.

* * * * *

(b) The Government shall make progress payments monthly as the work proceeds, or at more frequent intervals as determined by the Contracting Officer, on estimates of work accomplished which meets the standards of quality established under the contract, as approved by the Contracting Officer. * * *

* * * * *

(g) Notwithstanding any provision of this contract, progress payments shall not exceed 80 percent on work accomplished on undefinitized contract actions. A "contract action" is any action resulting in a contract, as defined in FAR Subpart 2.1, including contract modifications for additional supplies or services, but not including contract modifications that are within the scope and under the terms of the contract, such as contract modifications issued pursuant to the Changes clause, or funding and other administrative changes.

(End of clause)

23. Section 52.232–10 is amended by removing in the title of the clause the date "(JUL 1985)" and inserting in its place the date "(AUG 1987)"; by revising the first sentence in paragraph (a); and by adding paragraph (e) to read as follows:

52.232–10 Payments under fixed-price architect-engineer contracts.

* * * * *

(a) Estimates shall be made monthly of the amount and value of the work accomplished and services performed by the Contractor under this contract which meet standards of quality established under this contract.

* * * * *

(e) Notwithstanding any other provision in this contract, and specifically paragraph (b) of this clause, progress payments shall not exceed 80 percent on work accomplished on undefinitized contract actions. A "contract action" is any action resulting in a contract, as defined in FAR Subpart 2.1, including contract modifications for additional supplies or services, but not including contract modifications that are within the scope and under the terms of the contract, such as contract modifications issued pursuant to the Changes clause, or funding and other administrative changes.

(End of clause)

24. Section 52.232–16 is amended by removing in the title of the clause, and in the title of Alternate I and Alternate II the date "(APR 1984)" and inserting in each place the date "(AUG 1987); by removing in paragraph (a)(1)(i) of the clause the words "90 percent" and inserting in their place the words "80 percent"; by removing in paragraph (a)(5) and in the first sentence of paragraph (b) of the clause the words "90 percent" and inserting in their place the words "80 percent"; by revising paragraph (j)(3)(i) of the clause; by adding paragraph (k) to the clause; by removing both derivation lines following "(End of clause)" and each derivation line at the end of Alternate I and II; by revising the introductory text of Alternate I and II; by removing in paragraph (a)(1)(i) of Alternate I the words "95 percent" and inserting in their place the words "85 percent"; by redesignating and revising paragraph (k) in Alternate II as paragraph (1); and by adding paragraph (m) in Alternate II to read as follows:

52.232–16 Progress Payments

* * * * *

(j) * * *

(3) * * *

(i) Are substantially similar to the terms of the clause at 52.232–16, Progress Payments, for any subcontractor that is a large business concern, or that clause with its *Alternate I* for any subcontractor that is a small business concern;

* * * * *

(k) *Limitations on Undefinitized Contract Actions.* Notwithstanding any other progress payment provisions in this contract, progress payments may not exceed 80 percent of costs incurred on work accomplished under undefinitized contract actions. A "contract action" is any action resulting in a contract, as defined in Subpart 2.1, including contract modifications for additional supplies or services, but not including contract modifications that are within the scope and under the terms of the contract, such as contract modifications issued pursuant to the Changes clause, or funding and other administrative changes. This limitation shall apply to the costs incurred, as computed in accordance with paragraph (a) of this clause, and shall remain in effect until the contract action is definitized. Costs incurred which are subject to this limitation shall be segregated on Contractor progress payment

requests and invoices from those costs eligible for higher progress payment rates. For purposes of progress payment liquidation, as described in paragraph (b) of this clause, progress payments for undefinitized contract actions shall be liquidated at 80 percent of the amount invoiced for work performed under the undefinitized contract action as long as the contract action remains undefinitized. The amount of unliquidated progress payments for undefinitized contract actions shall not exceed 80 percent of the maximum liability of the Government under the undefinitized contract action or such lower limit specified elsewhere in the contract. Separate limits may be specified for separate actions.

(End of clause)

Alternate I (AUG 1987). If the contract is with a small business concern, change each mention of the progress payment and liquidation rates excepting paragraph (k) to the customary rate of 85 percent for small business concerns (see 32.501–1), delete subparagraphs (a)(1) and (a)(2) from the basic clause, and substitute the following subparagraphs (a)(1) and (a)(2):

* * * * *

Alternate II (AUG 1987). If the contract is a letter contract, add paragraphs (l) and (m). The amount specified in paragraph (m) shall not exceed 80 percent applied to the maximum liability of the Government under the letter contract. Separate limits may be specified for separate parts of the work.

(l) Progress payments made under this letter contract shall, unless previously liquidated under paragraph (b) of this clause, be liquidated under the following procedures:

(1) If this letter contract is superseded by a definitive contract, unliquidated progress payments made under this letter contract shall be liquidated by deducting the amount from the first progress or other payments made under the definitive contract.

(2) If this letter contract is not superseded by a definite contract calling for the furnishing of all or part of the articles or services covered under the letter contract, unliquidated progress payments made under the letter contract shall be liquidated by deduction from the amount payable under the Termination clause.

(3) If this letter contract is partly terminated and partly superseded by a contract, the Government shall allocate the unliquidated progress payments to the terminated and unterminated portions as the Government deems equitable, and shall liquidate each portion under the relevant procedure in subparagraphs (l)(1) and (l)(2) of this clause.

(4) If the method of liquidating progress payments provided in this clause does not result in full liquidation, the Contractor shall immediately pay the unliquidated balance to the Government on demand.

(m) The amount of unliquidated progress payments shall not exceed . . . . *(specify dollar amount).*

25. Section 52.243–1 is amended by revising the introductory text; by removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(AUG 1987)"; by revising the first sentence of paragraph (c) of the clause; and by removing the derivation lines following "(End of clause)" to read as follows:

52.243–1 Changes—Fixed Price.

As described in 43.205(a)(1), insert the following clause. The 30–day period may be varied according to agency procedures.

* * * * *

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. * * *

* * * * *

26. Section 52.243–2 is amended by revising the introductory text; by removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(AUG 1987)"; by revising the first sentence of paragraph (c) of the clause; and by removing the derivation lines following "(End of clause)" to read as follows:

52.243–2 Changes—Cost-Reimbursement.

As prescribed in 43.205(b)(1), insert the following clause. The 30–day period may be varied according to agency procedures.

* * * * *

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. * * *

* * * * *

27. Section 52.243–3 is amended by revising the introductory text; by removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(AUG 1987)"; by revising the first sentence of paragraph (c) of the clause; and by removing the derivation lines following "(End of clause)" to read as follows:

52.243–3 Changes—Time-and-Materials or Labor-Hours.

As prescribed in 43.205(c), insert the following clause. The 30-day period may be varied according to agency procedures.

* * * * *

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. * * *

* * * * *

28. Section 52.243–4 is amended by revising the introductory text; by removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(AUG 1987)"; by revising the second sentence of paragraph (d) of the clause; by revising the first sentence of paragraph (e) of the clause; and by removing the derivation lines following "(End of clause)" to read as follows:

52.243–4 Changes.

As prescribed in 43.205(d), insert the following clause. The 30–day period may be varied according to agency procedures.

* * * * *

(d) * * * However, except for an adjustment based on defective specifications, no adjustment for any change under paragraph (b) of this clause shall be made for any costs incurred more than 20 days before the Contractor gives written notice as required. * * *

(e) The Contractor must assert its right to an adjustment under this clause within 30 days after (1) receipt of a written change order under paragraph (a) of this clause or (2) the furnishing of a written notice under paragraph (b) of this clause, by submitting to the Contracting Officer a written statement describing the general nature and amount of proposal, unless this period is extended by the Government. * * *

* * * * *

PART 53—FORMS

29. Section 53.249 is amended by revising paragraph (a)(3) to read as follows:

53.249 Termination of contracts (SF's 1034 and 1435 through 1440).

(a) * * *

(3) SF 1436 (10/83), Settlement Proposal (Total Cost Basis). (See 49.602–1(b).) Pending publication of a new edition of SF 1436, Item 7, Section II, is revised to read "Total Costs (Items 1 thru 6)."

* * * * *

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Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 872

Medical Devices; Dental Devices Classification; Final Rule and Withdrawal of Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 872

[Docket No. 78N-2830]

Dental Devices; General Provisions and Classifications of 110 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 110 dental devices. The preamble to this rule responds to comments received on the proposed regulations regarding classification of these devices. These actions are being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: September 11, 1987.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Background

In the **Federal Register** of December 30, 1980 (45 FR 85962-86168), FDA published proposed regulations containing general provisions applicable to the classification of dental devices and individual proposed regulations to classify dental devices in commercial distribution into one or more of three regulatory classes: Class I (general controls), class II (performance standards), and class III (premarket approval).

In this final rule, FDA is classifying 110 devices as follows: 53 devices into class I, 42 devices into class II, 10 devices into class III, and, depending upon a variety of factors, such as intended uses or composition of the devices, 2 devices into class I or class II, 2 devices into class I or class III, and 1 device into class II or class III. To reduce printing costs, FDA is publishing the general provisions and the classifications in one final rule. FDA previously published a separate proposed classification rule and final classification rule for each device.

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. 301-392). The effect of classifying a device into 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 into 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. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before February 28, 1990, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. 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, 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), 360c(f)).

The preamble to the proposed regulations described the development of the general provisions and the proposed regulations classifying dental devices and the activities of the Dental Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, now the Dental Devices Panel (the Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of dental devices. FDA provided a period of 60 days, later extended to 90 days (March 6, 1981; 46 FR 15519), for interested persons to submit written comments on the proposals. The comments received and FDA's responses to the comments 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 required by section 514 of the act. If legislation comparable to this bill becomes law, there would be only two categories of devices: class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because the proposed legislation contains transitional provisions that convert classifications under the current law to classifications under the proposed law, FDA is continuing to issue 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 III 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 the devices already classified (or being classified) in class II. Under the amendments, FDA is using the regulatory controls of class I to regulate a device classified into class II until a performance standard is established under section 514 of the act (21 U.S.C. 360d) for a class II device. In the notice above FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices:

a. 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;

b. The recommendations of FDA's advisory committees;

c. The impact of an FDA guideline or recommendation;

d. The effect of a Federal standard or other regulatory controls under an authority other than the act;

e. The impact of voluntary standards;

f. The impact of activities authorized under the general controls provisions of the act;

g. The effect of dissemination of information and education efforts;

h. The sufficiency of voluntary corrective actions;

i. Valid scientific evidence developed since classification;

j. The existence of a petition for reclassification;

k. The impact of any other factors that affect a device's safety or effectiveness.

C. Changes in the Name of the Dental Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Dental Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to dental devices as did its predecessors, the Dental Device Classification Panel (1976–1978) and the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel (1978–1984). Because of several changes in the membership of the advisory committee for dental devices that occurred after the committee had made its classification recommendations, during July 1981, FDA requested the committee to review its original classification recommendations. The new committee reaffirmed all but two of the old committee's recommendations (see paragraphs 11 and 13 of this preamble for the changes).

D. Grouping of Similar Devices—Withdrawal of 67 Dental Proposed Regulations Because of Different Grouping

In this final rule, FDA has grouped together similar devices, thereby reducing the number of separate dental device classifications. FDA issued proposals on 185 devices and is issuing final classifications now on 110 devices, with 10 additional classifications planned in the future.

FDA has now grouped 89 dental devices that were the subjects of FDA's proposals as separate generic types of devices into 22 generic types of devices, thus eliminating the need for 67 final classifications. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing the 67 proposed dental device classification regulations that now are unnecessary due to the new grouping of dental devices. The remaining 96 generic types of devices that were the subjects of proposals are unaffected by this regrouping. The term "generic type of device" is defined in 21 CFR 860.3(i). Dental devices that are grouped into one generic type of device do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety or effectiveness. Consequently, similar regulatory controls are appropriate to provide reasonable assurance of the safety and effectiveness of these devices. FDA has made appropriate changes in the identification of each device being grouped in order to identify more accurately the generic type of device.

The devices being grouped differently from the proposals are identified in this preamble below under "F. LIST OF DENTAL DEVICES." Each generic type of dental device is identified with both the docket number or numbers used for that device in the proposed regulations and the section number of the Code of Federal Regulations at which its classification is being codified. A device listed in the "List of Dental Devices" that is not identified with a section number is being grouped into the generic type of device with a section number listed directly before it. (Thus, for example, *Gold based alloy for clinical use* and *Precious metal alloy for clinical use* are being grouped into the generic type of device *Gold based alloys and precious metal alloys for clinical use* (§ 872.3060)).

The new grouping of dental devices results in 118 generic types of dental devices (185 proposals minus 67 unnecessary proposals). FDA is postponing for now its final classifications of 10 generic types of electrically powered dental devices pending the agency's review of additional data concerning electrical safety (see the next section of this preamble, "E. DENTAL DEVICES NOT BEING CLASSIFIED AT THIS TIME"). Thus, the number of generic types of dental devices based on the 1980 proposals that are being classified in this rule is 108.

Also, in this final rule, FDA is codifying the classifications of two devices that, under applicable statutory procedures, need not have been subjects of proposed classification rules (see the discussions under "K. CODIFICATION OF TWO DEVICES NOT SUBJECTS OF DENTAL PROPOSED REGULATIONS"). With these two additional classifications, in this rule FDA is classifying 110 generic types of dental devices.

E. Dental Devices not Being Classified at This Time

FDA is postponing classification of the following 10 generic types of dental devices in order to review additional data on electrical safety. FDA is considering reproposing these devices for classification into class I. Because of the grouping of similar dental devices as described above, the 10 generic types of devices encompass devices that were the subjects of 20 proposed regulations. The following is a list of the 10 generic types of dental devices that are not being classified in this final rule:

Mechanical denture cleaner
Dental handpiece and accessories
Dental chair with or without operative unit
Oral irrigation unit
Dental operative unit and accessories
Powered toothbrush
AC-powered dental amalgamator
Fiber optic dental light
Heat source for bleaching teeth
Boiling water sterilizer

F. List of Dental Devices

The list below shows, for each dental device, the section of the Code of Federal Regulations at which the classification of that device is being codified (or will be codified), the docket number or numbers of any corresponding proposed classification regulation, and the final classification of the device.

The list includes the 10 generic types of dental devices for which final classification is being postponed. For each of these 10 devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "2", and no final classification is provided.

Section	Device	Docket No.	Class
	SUBPART B—DIAGNOSTIC DEVICES		
872.1500	Gingival fluid measurer	78N-2831	I
872.1720	Pulp tester	78N-2834	II
872.1730	Electrode gel for pulp tester	78N-2835	I

Section	Device	Docket No.	Class
872.1740	Caries detection device	80P-0064	II [1]
872.1800	Extraoral source X-ray system	78N-2836	II
872.1810	Intraoral source X-ray system	78N-2837	II
872.1820	Dental X-ray exposure alignment device	78N-2838	I
872.1830	Cephalometer	78N-2839	II
872.1840	Dental X-ray position indicating device	78N-2840	II
872.1850	Lead-lined position indicator	78N-2841	II
872.1905	Dental X-ray film holder	78N-2842	I
	SUBPART D—PROSTHETIC DEVICES		
872.3050	Amalgam alloy	78N-2843	II
872.3060	Gold based alloys and precious metal alloys for clinical use	78N-2844	II
	Gold based alloy for clinical use	78N-2844	
	Precious metal alloy for clinical use	78N-2845	
872.3080	Mercury and alloy dispenser	78N-2846	I
(872.3100)	AC-powered dental amalgamator [2]	78N-2847	
872.3110	Dental amalgam capsule	78N-2848	I
872.3130	Performed anchor	78N-2849	I
872.3140	Resin applicator	78N-3024	I
872.3150	Articulator	78N-2850	I
872.3165	Precision attachment	78N-2851	I
	Precision attachment	78N-2851	
	Preformed bar	78N-2852	
872.3200	Resin tooth bonding agent	78N-2853	II
872.3220	Facebow	78N-2854	I
872.3240	Dental bur	78N-2855	I
872.3250	Calcium hydroxide cavity liner	78N-2856	II
872.3260	Cavity varnish	78N-2857	II
872.3275	Dental cement	78N-2858	I, II
	Dental cement	78N-2858	
	Zinc oxide eugenol	78N-2913	
872.3285	Preformed clasp	78N-2859	I
	Preformed clasp	78N-2859	
	Preformed wire clasp	78N-2860	
872.3300	Hydrophilic resin coating for dentures	78N-2861	II
872.3310	Coating material for resin fillings	78N-2862	II
872.3330	Preformed crown	78N-2863	I
872.3350	Gold or stainless steel cusp	78N-2864	I
872.3360	Preformed cusp	78N-2865	I
872.3400	Karaya and sodium borate with or without acacia denture adhesive	78N-2866	I, III
	Acacia and karaya with sodium borate denture adhesive	78N-2866	
	Karaya with sodium borate denture adhesive	78N-2873	
872.3410	Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive	78N-2867	I
	Carboxymethylcellulose sodium (40 to 100%) denture adhesive	78N-2867	
	Carboxymethylcellulose sodium (32%) and ethylene oxide homopolymer (13%) denture adhesive	78N-2869	
	Carboxymethylcellulose sodium (49%) and ethylene oxide homopolymer (21%) denture adhesive	78N-2870	
872.3420	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive	78N-2868	III
872.3450	Ethylene oxide homopolymer and/or karaya denture adhesive	78N-2871	I
	Karaya denture adhesive	78N-2871	
	Karaya and ethylene oxide homopolymer denture adhesive	78N-2872	
872.3480	Polyacrylamide polymer (modified cationic) denture adhesive	78N-2874	III
872.3490	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.	78N-2875	I
	Polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive	78N-2875	
	Polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesive.	78N-2877	
872.3500	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.	78N-2876	III
872.3520	OTC denture cleanser	78N-2878	I
(872.3530)	Mechanical denture cleaner [2]	78N-2879	
872.3540	OTC denture cushion or pad	78N-2880	I, III
	OTC denture cushion	78N-2880	
	OTC denture pad	78N-2881	
872.3560	OTC denture reliner	78N-2882	III
872.3570	OTC denture repair kit	78N-2883	III
872.3580	Preformed gold denture tooth	78N-2884	I
872.3590	Preformed plastic denture tooth	78N-2885	II
872.3600	Partially fabricated denture kit	78N-2866	III
872.3640	Endosseous implant	78N-2887	III
872.3645	Subperiosteal implant material	78N-2888	II
	Titanium subperiosteal implant material	78N-2888	
	Cobalt chrome molybdenum subperiosteal implant material	78N-2889	
872.3660	Impression material	78N-2890	II

Section	Device	Docket No.	Class
872.3670	Resin impression tray material	78N-2891	I
872.3680	Polytetrafluoroethylene (PTFE) vitreous carbon material	78N-2892	II
872.3690	Tooth shade resin material	78N-2893	II
872.3700	Dental mercury	78N-2894	I
872.3710	Base metal alloy	78N-2895	II
872.3730	Pantograph	78N-2897	I
872.3740	Retentive and splinting pin	78N-2898	I
872.3750	Bracket adhesive resin and tooth conditioner	78N-2899	II
872.3760	Denture relining, repairing, or rebasing resin	78N-2900	II
872.3765	Pit and fissure sealant and conditioner	78N-2901	II
872.3770	Temporary crown and bridge resin	78N-2902	II
872.3810	Root canal post	78N-2904	I
872.3820	Root canal filling resin	78N-2905	II, III
872.3830	Endodontic paper point	78N-2906	I
872.3840	Endodontic silver point	78N-2907	I
872.3850	Gutta percha	78N-2908	I
872.3890	Endodontic stabilizing splint	78N-2909	II
872.3900	Posterior artificial tooth with a metal insert	78N-2910	I
872.3910	Backing and facing for an artificial tooth	78N-2911	I
872.3920	Porcelain tooth	78N-2912	II
872.3930	Tricalcium phosphate granules for dental bone repair		III [3]
	SUBPART E—SURGICAL DEVICES		
872.4120	Bone cutting instruments and accessories	78N-2915	II
	Manual bone drill and wire driver	78N-2915	
	Powered bone drill	78N-2917	
	Rotary bone cutting handpiece	78N-2920	
	AC-powered bone saw	78N-2941	
872.4130	Intraoral dental drill	78N-2916	I
(872.4200)	Dental handpiece and accessories [2]	78N-2918	
	Air-powered dental handpiece	78N-2918	
	Belt-driven dental handpiece	78N-2919	
	Contra angle handpiece attachment	78N-2921	
	Direct drive handpiece	78N-2922	
	Foot controller for handpiece	78N-2923	
	Water-powered handpiece	78N-2924	
872.4465	Gas-powered jet injector	78N-2925	II
872.4475	Spring-powered jet injector	78N-2926	II
872.4535	Dental diamond instrument	78N-2929	I
872.4565	Dental hand instrument	78N-2931	I
	Dental hand instrument	78N-2931	
	Endodontic broach	78N-3027	
	Dental wax carver	78N-2914	
	Endodontic pulp canal file	78N-3026	
	Hand instruments for calculus removal	78N-2927	
	Dental depth gauge instrument	78N-2928	
	Plastic dental filling instrument	78N-2930	
	Dental instrument handle	78N-2932	
	Surgical tissue scissors	78N-2945	
	Orthodontic band driver	78N-2952	
	Orthodontic band pusher	78N-2954	
	Orthodontic band setter	78N-2955	
	Orthodontic bracket aligner	78N-2958	
	Orthodontic pliers	78N-2962	
	Orthodontic ligature tucking instrument	78N-2967	
	Forceps for articulation paper	78N-2990	
	Forceps for dental dressing	78N-2991	
	Dental matrix band	78N-2997	
	Matrix retainer	78N-2998	
	Mouth mirror	78N-3000	
	Dental retractor	78N-3007	
	Dental retractor accessories	78N-3008	
	Periodontic or endodontic irrigating syringe	78N-3016	
	Restorative or impression material syringe	78N-3017	
872.4600	Intraoral ligature and wire lock	78N-2933	II
(872.4620)	Fiber optic dental light [2]	78N-2934	
872.4630	Dental operating light	78N-2935	II
	Dental operating light	78N-2935	
	Surgical headlight	78N-2936	
872.4730	Dental injecting needle	78N-2937	I
872.4760	Bone plate	78N-2938	II
872.4840	Rotary scaler	78N-2942	II
872.4850	Ultrasonic scaler	78N-2943	II

Section	Device	Docket No.	Class
872.4880	Intraosseous fixation screw or wire	78N-2946	II
	Intraosseous fixation screw	78N-2946	
	Intraosseous fixation wire	78N-2948	
872.4920	Dental electrosurgical	78N-2947	II
	SUBPART F—THERAPETIC DEVICES		
872.5410	Orthodontic appliance and accessories	78N-2951	I
	Preformed orthodontic band	78N-2951	
	Orthodontic elastic band	78N-2950	
	Orthodontic band material	78N-2953	
	Orthodontic metal bracket	78N-2956	
	Orthodontic wire clamp	78N-2959	
	Preformed orthodontic space maintainer	78N-2961	
	Orthodontic expansion screw retainer	78N-2963	
	Orthodontic spring	78N-2964	
	Orthodontic tube	78N-2966	
	Orthodontic wire	78N-2968	
872.5470	Orthodontic plastic bracket	78N-2957	II
872.5500	Extraoral orthodontic headgear	78N-2960	II
872.5525	Preformed tooth positioner (proposed as § 872.5575)	78N-3025	I
872.5550	Teething ring	78N-2965	I, II
	SUBPART G—MISCELLANEOUS DEVICES		
872.6010	Abrasive device and accessories	78N-2969	I
	Abrasive disk	78N-2969	
	Guard for an abrasive disk	78N-2993	
	Abrasive point	78N-2970	
	Polishing agent strip	78N-2972	
	Polishing wheel	78N-2973	
872.6030	Oral cavity abrasive polishing agent	78N-2971	I
872.6050	Saliva absorber	78N-2974	I
	Paper saliva absorber	78N-2974	
	Cotton roll	78N-2982	
872.6070	Ultraviolet activator for polymerization	78N-2975	II
872.6080	Airbrush	78N-2976	III
872.6100	Anesthetic warmer	78N-2977	I
872.6140	Articulation paper	78N-2978	I
872.6200	Base plate shellac	78N-2979	I
(872.6250)	Dental chair with or without operative unit [2]	78N-2980	
	Dental chair with operative unit	78N-2980	
	Dental chair without operative unit	78N-2981	
872.6290	Prophylaxis cup	78N-2983	I
872.6300	Rubber dam and accessories	78N-2984	I
	Rubber dam	78N-2984	
	Rubber dam clamp	78N-2985	
	Rubber dam frame	78N-2986	
	Forceps for a rubber dam clamp	78N-2992	
872.6350	Ultraviolet detector	78N-2987	II
872.6390	Dental floss	78N-2989	I
(872.6475)	Heat source for bleaching teeth [2]	78N-2994	
(872.6510)	Oral irrigation unit [2]	78N-2996	
872.6570	Impression tube	78N-2999	I
(872.6640)	Dental operative unit and accessories [2]	78N-3002	
	Dental operative unit	78N-3002	
	Saliva ejector mouthpiece	78N-3001	
	Oral cavity evacuator	78N-2988	
	Suction operative unit	78N-3003	
	Air or water syringe unit	78N-3012	
872.6650	Massaging pick or tip for oral hygiene	78N-3004	I
	Massaging pick	78N-3004	
	Rubber tip for oral hygiene	78N-3018	
872.6660	Porcelain powder for clinical use	78N-3005	II
872.6670	Silicate Protector	78N-3006	I
(872.6710)	Boiling water sterilizer [2]	78N-3009	
872.6730	Endodontic dry heat sterilizer	78N-3011	III
872.6770	Cartridge syringe	78N-3014	II
872.6855	Manual toothbrush	78N-3019	I
(872.6865)	Powered toothbrush [2]	78N-3020	
872.6870	Disposable fluoride tray	78N-3021	I
872.6880	Preformed impression tray	78N-3022	I
872.6890	Intraoral dental wax	78N-3023	I

[1] Not proposed; classification results from FDA's decision on a reclassification petition.
[2] Classification postponed.
[3] Not proposed; statutory classification.

G. Changes in Classifications

Based on the comments received and on additional consideration of all information before the agency, FDA has placed several devices in different classes from those originally proposed. FDA's reasons for adopting classifications for these devices that differ from the proposals are provided in this preamble in the section that follows. FDA believes that it is not necessary to issue a new proposal concerning these decisions. 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, the agency may be persuaded 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 regulation on dental devices (see 45 FR 85964). In addition, many of the final classifications that differ from FDA's proposed classifications are consistent with the recommendations of the Panel. These recommendations were published in the preambles to the proposed rules and thus foreshadowed the changes now being made. Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

H. Summary of Comments on Classifications and FDA's Responses

To clarify the final rule and save printing costs, FDA is responding once to comments that apply to more than one dental device. In such cases, FDA's response identifies the devices to which the comment and response apply.

1. Many comments on the proposed regulations requested that FDA classify each dental device into the class recommended by the Panel.

FDA's final classification rule accomplishes many, but not all, of the changes desired by these general comments. Of the 185 devices that were the subjects of the proposed regulations, FDA proposed to classify 108 devices (58 percent) into the class recommended by the Panel. Taking into account the Panel's later changes in its recommendations on two devices (see paragraphs 11 and 13 of this preamble) and omitting the 10 final classifications which are being postponed, in this final rule FDA is classifying about 89 percent of the devices into the class recommended by the Panel. FDA is making available (Ref. 12) in its Docket Management Branch (address below) a detailed matrix that shows for each device how the Panel's recommendations compare to FDA's proposed and final classifications.

2. Many comments requested that FDA classify into class I most of the 124 dental devices that FDA proposed to classify into class II.

FDA agrees in part and disagrees in part with the comments. For many of the 77 devices that the Panel recommended be placed in class I but which FDA proposed to classify into class II, FDA now agrees that the correct class is class I. Accordingly, in the final rule the agency is classifying many of these devices into class I. However, the Panel recommended and FDA proposed that 47 dental devices be classified into class II. For many of these 47 devices, FDA disagrees with the comments requesting that these devices be placed into class I. In the paragraphs below, FDA is providing its reasons for agreeing or disagreeing with these comments with respect to specific devices.

3. In addition to the comments discussed above in paragraphs 1 and 2, specific comments on the proposed regulations on the devices discussed below argued that the agency did not identify any substantive risks to health associated with the devices that would justify classifying them into class II, as was proposed by FDA. The section had recommended that these devices be classified into class I, with the exception of the dental diamond instrument (§ 872.4535) and hand instrument for calculus removal (Docket No. 78N–2927), which the section had recommended be classified into class II.

Comments stated that the agency cited no adverse experience data or complaint data to support the proposed classifications. The comments reasoned that the devices should be classified into class I because manufacturers have distributed these devices for many years without FDA controls and because they are safe and effective. FDA has considered these comments in the classification decisions described below.

3a. Dental x-ray exposure alignment device (§ 872.1820).

FDA now believes that the dental x-ray exposure alignment device, an accessory to a dental x-ray system, should be classified into class I. FDA proposed to classify the device into class II because of concern about improper x-ray beam alignment that, in some instances, may cause the operator of the dental x-ray system to repeat x-rays of patients. If x-rays have to be repeated, the patient would receive unnecessary radiation. However, FDA now believes that the accuracy of dental x-ray beam alignment depends almost entirely on the skills of the operator of the dental x-ray system, and only a limited portion of the risk of improper x-ray beam alignment results from the design and function of the dental x-ray exposure alignment device. FDA believes that it is unnecessary to establish performance standards for the dental x-ray exposure alignment device, because the essential portion of the risk to health of improper alignment of the x-ray beam would not be significantly reduced through establishment of a standard for the accessory device. FDA believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is classifying the dental x-ray exposure alignment device into class I.

3b. Dental retractor (Docket No. 78N–3007); dental retractor accessories (Docket No. 78N–3008); and dental x-ray film holder (§ 872.1905).

FDA now believes that the three devices above should be classified into class I. FDA proposed to classify these devices into class II because of concerns about microbial contamination of the reusable devices that may cause infections in patients. FDA now believes that the essential risk to health from microbial contamination of these reusable devices is controlled by the skill and conscientiousness of the users of these devices in maintaining the cleanliness of the devices and sterilizing them between uses. FDA believes that it is unnecessary to establish performance standards for the devices above, because the essential risk to health (microbial contamination) would not be reduced through establishment of standards. FDA believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of these devices, particularly the controls of the current good manufacturing practice (CGMP) regulations in Part 820. Accordingly, FDA is classifying the dental retractor, dental retractor accessories, and the dental x-ray film holder into class I.

3c. Mercury and alloy dispenser (§ 872.3080) and dental amalgam capsule (§ 872.3110).

FDA now believes that the mercury and alloy dispenser and the dental amalgam capsule should be classified into class I. FDA proposed to classify the devices above into class II because of concern about the accuracy of measurements of materials by the

mercury and alloy dispenser, and concern that both devices might leak mercury that may cause toxic reactions. FDA now believes that the risk to health of patients presented by inaccurate measurements of materials by the mercury and alloy dispenser is minimal and this risk would be controlled by manufacturers' adherence to the CGMP regulations. FDA also believes that manufacturers' adherence to the CGMP regulations for these devices would control the potential for leakage of mercury from the devices that could pose a risk to health of dental practitioners. (See also paragraph 5 for a discussion of classification of dental mercury.) Thus, FDA now believes that it is unnecessary to establish performance standards for the two devices, because the devices present a low risk to health of patients, and these risks would not be significantly reduced through establishment of such standards. FDA believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of the two devices, particularly the controls of the CGMP regulations in Part 820. Accordingly, FDA is classifying the mercury and alloy dispenser and the amalgam capsule into class I.

3d. Intraoral dental drill (§ 872.4130) and dental diamond instrument (§ 872.4535).

FDA now believes that the intraoral dental drill and the dental diamond instrument should be classified into class I. FDA proposed to classify the devices into class II because of concerns about the strength and hardness of the intraoral dental drill and the possibility of inadequate abrasive properties of the dental diamond instrument. Both devices are intended to cut human teeth. FDA now believes that minimal risk to the health of patients would result, if the intraoral dental drill were to lack strength and hardness or if the dental diamond instrument were to lack certain abrasive properties. FDA also believes that these risks to health would be controlled through the general controls of class I, particularly manufacturers' adherence to the CGMP regulations in Part 820. FDA now believes that is is unnecessary to establish performance standards for the devices. FDA believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of the devices. Accordingly, FDA is classifying the intraoral dental drill and the dental diamond instrument into class I.

3e. Hand instrument for calculus removal (Docket No. 78N-2927).

FDA now believes that the hand instrument for calculus removal should be classified into class I. FDA proposed to classify the device into class II because of concern that improper design of the device might cause unnecessary trauma to gum tissue and concern that lack of biocompatibility of the device might cause adverse tissue reactions. (FDA is discussing the latter concern in paragraph 3f., below.) FDA now believes that minimal risk to health would result, if this hand-held device were to have an improper design. The device is intended for use by dental health professionals experienced in its use. Trauma to a patient's gums from use of the device is essentially controlled by the skills of the professional using it, and the device itself would rarely, if ever, be responsible for unnecessary gum trauma. Thus, FDA believes that it is unnecessary to establish performance standards to control the design of the device, because the essential portion of the risk to health of unnecessary gum trauma would not be reduced through establishment of standards for the device. FDA believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of the hand instrument for calculus removal. Accordingly, FDA is classifying the device into class I.

3f. FDA now believes that the devices listed below should be classified into class I. FDA proposed to classify the devices into class II because of concerns about possible bioincompatibility of the devices, resulting in adverse tissue reactions. However, FDA now believes that in 1980, when it proposed to classify these devices, the agency assigned to the devices a higher level of risk of bioincompatibility than was justified by the years of experience of dentists and patients with these devices.

Thus, FDA now believes that it is unnecessary to establish performance standards for the devices listed below to control the risk of bioincompatibility, because FDA believes that these devices present only minimal risks of bioincompatibility and that these minimal risks would not be significantly reduced through establishing performance standards for these devices due to the idiosyncratic nature of individual sensitivities. FDA believes that the general controls of class I would provide reasonable assurance of the safety and effectiveness of the devices. The labeling of a device that causes sensitivity reactions in some individuals should be so labeled, to be in compliance with the misbranding provisions (21 U.S.C. 352) of the general controls of the act. Accordingly, FDA is classifying the devices listed below in class I.

Section	Device/Docket No.
872.1730	Electrode gel for pulp tester.
872.3410	Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.
	Carboxymethylcellulose sodium (40 to 100%) denture adhesive (Docket No. 78N-2867).
	Carboxymethylcellulose sodium (32%) and ethylene oxide homopolymer (13%) denture adhesive (Docket No. 78N-2869).
	Carboxymethylcellulose sodium (49%) and ethylene oxide homopolymer (21%) denture adhesive (Docket No. 78N-2870).
872.3450	Ethylene oxide homopolymer and/or karaya denture adhesive.
	Karayra denture adhesive (Docket No. 78N-2871).
	Karaya and ethylene oxide homopolymer denture adhesive (Docket No. 78N-2872).
872.3490	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.
	Polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (Docket No. 78N-2875).
	Polyvinylmethylether maleic acid calcium-sodium double salt carboxymethylcellulose sodium denture adhesive (Docket No. 78N-2877).
872.3520	OTC denture cleanser.
872.3830	Endodontic paper point.
872.3840	Endodontic silver point.
872.3850	Gutta percha.
872.4565	Dental hand instrument.
	Endodontic broach (Docket No. 78N-3027).
	Endodontic pulp canal file (Docket No. 78N-3026).
.....	Surgical tissue scissors (Docket No. 78N-2951).
872.5410	Orthodontic appliances accessories.
	Preformed orthodontic band (Docket No. 78N-2951).
	Orthodontic elastic band (Docket No. 78N-2950).
	Orthodontic band material (Docket No. 78N-2953).
	Orthodontic metal bracket (Docket No. 78N-2956).
	Orthodontic wire clamp (Docket No. 78N-2959).
	Preformed orthodontic space maintainer (Docket No. 78N-2961).
	Orthodontic expansion screw retainer (Docket No. 78N-2963).
	Orthodontic spring (Docket No. 78N-2964).
	Orthodontic tube (Docket No. 78N-2966).
	Orthodontic wire (Docket No. 78N-2968).
872.5525	Preformed tooth positioner.

Section	Device/Docket No.
872.6010	Abrasive device and accessories. Abrasive disk (Docket No. 78N-2969). Abrasive point (Docket No. 78N-2970). Polishing agent strip (Docket No. 78N-2972).
872.6030	Oral cavity abrasive polishing agent.
872.6200	Base plate shellac.

FDA advises that the devices listed above that are identified by a common docket number have been grouped. See the information under the heading "D. Grouping of Similar Devices—Withdrawal of 67 Dental Proposed Regulations Because of Different Grouping," earlier in this preamble.

4. Zinc oxide eugenol; Docket No. 78N-2913; proposed class II; § 872.3275; dental cement; proposed class II. Many comments recommended that zinc oxide eugenol be classified into class I because it has been used for a long time without any problems.

4a. Zinc oxide eugenol. FDA now believes that zinc oxide eugenol should be classified into class I. FDA proposed to classify the device into class II because of concerns about possible bioincompatibility of the device resulting in adverse tissue reactions. However, FDA now believes that in 1980, when it proposed to classify the device, the agency assigned to the device a higher level of risk of bioincompatibility than was justified by the years of experience of dentists and patients with the device. Thus, FDA now believes that it is unnecessary to establish a performance standard for zinc oxide eugenol to control the risk of bioincompatibility, because the device presents only minimal risks of bioincompatibility and that these minimal risks would not be significantly reduced through establishing a performance standard for the device due to the idiosyncratic nature of individual sensitivities. The labeling of a device that causes sensitivity reactions in some individuals should be so labeled to be in compliance with the misbranding provisions (21 U.S.C. 352) of the general controls of the act. FDA now believes that the general controls of class I alone would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is classifying zinc oxide eugenol into class I.

4b. Dental cement. FDA proposed that dental cement, including zinc oxide eugenol dental cement, be classified into class II because materials used in the device should meet a generally accepted and satisfactory level of biocompatibility. FDA believes that a performance standard is necessary for dental cement other than zinc oxide eugenol, because general controls alone are insufficient to control the risks to health presented by this device. The agency believes that a performance standard would provide reasonable assurance of the safety and effectiveness of dental cement other than zinc oxide eugenol, and that sufficient information is available to establish a performance standard for dental cement other than zinc oxide eugenol.

Zinc oxide eugenol was identified in two proposed regulations (§ 872.3980, Docket No. 78N-2913 and § 872.3275, Docket No. 78N-2858). In the final rule, FDA is treating zinc oxide eugenol as a subtype of the generic type of device dental cement (§ 872.3275). Accordingly, FDA is classifying zinc oxide eugenol (including zinc oxide eugenol dental cement) into class I and classifying dental cement other than zinc oxide eugenol into class II.

5. Section 872.3700; Dental mercury; proposed class II. Comments recommended that dental mercury be classified into class I instead of class II as proposed. The comments acknowledged that elemental mercury is a poison, but stated that the risks to health presented to dentists and other dental workers are inherent in the device and would not be reduced through establishment of performance standards for the device. The comments also stated that manufacturers have voluntarily accomplished several actions to protect dentists and other dental workers from the inherent risks presented by the device, such as packaging the device in leak-proof containers and placing cautionary statements in the labeling of the device.

FDA agrees with comments urging that this device be classified into class I. As stated in the proposed regulation, FDA believes that presently there is no valid scientific evidence of systemic poisoning to patients exposed to amalgam containing mercury. FDA acknowledges that the device presents a risk to those few patients who experience allergic reactions to this material, as evidenced by rare reports of such reactions (Refs. 9, 10, and 11), and to individuals such as dentists who regularly handle dental mercury. Upon further consideration, FDA now believes that labeling for the device bearing adequate directions for use and warnings under the misbranding provisions (21 U.S.C. 352) of the general controls of the act would warn dentists about the rare risk of allergic reactions among patients and the risk of toxicity to dental health professionals. Establishing a performance standard for dental mercury would do nothing to reduce these risks. Thus, FDA believes that the general controls of class I alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device and that it is unnecessary to establish performance standards for the device. Accordingly, FDA is classifying the device into class I.

6. Section 872.5550; Teething ring; proposed class I or class II depending upon the construction of the device. FDA received comments stating that (a) teething rings should not be considered a medical device, (b) problems with the use of teething rings do not exist, and (c) teething rings pose no hazards to health and, therefore, should be in class I.

FDA agrees in part and disagrees in part with these comments. With regard to the first comment, FDA has determined that it will regulate as medical devices only those teething rings (fluid-filled or solid) for which medical claims are made. Teething rings without medical claims are under the regulatory authority of the Consumer Product Safety Commission (CPSC). Most teething rings are not marketed with medical claims. Thus, the vast majority of teething rings are subject to the CPSC's jurisdiction rather than FDA's jurisdiction.

With regard to the second and third comments, FDA disagrees with the comments as applied to the fluid-filled version of this device. FDA proposed that the fluid-filled teething rings (such as one containing water) for which medical claims are made be classified into class II because FDA has received reports of microbial contamination of fluid-filled teething rings (Ref. 5). An infant who bites and ruptures a fluid-filled teething ring with contaminated contents could develop an infection. FDA continues to believe, therefore, that a performance standard is necessary to control risks to infant health if the fluid in the device is contaminated with microbes. Accordingly, FDA is classifying into class II fluid-filled teething rings for which medical claims are made.

FDA is classifying solid teething rings for which medical claims are made into class I, as proposed.

7. Section 872.4240; Rotary bone cutting handpiece; proposed class II: A comment noted that the rotary bone cutting handpiece is intended to operate at slower speeds than the regular "high speed" handpiece that FDA also

proposed to classify into class II. The comment suggested, therefore, that the rotary bone cutting handpiece should be classified into class I because it presents less risk to health than the "high speed" (air-powered) handpiece (78N-2918) and because the risk to health identified by the Panel, i.e., unnecessary trauma, cannot be controlled by a performance standard.

FDA disagrees with the comment. FDA believes that a performance standard is necessary for this device to assure that its design will not cause bone damage or tissue trauma and that the risk to health can be controlled by a performance standard. Accordingly, FDA is classifying the device into class II.

8. Section 872.4820; AC-powered bone saw; proposed class II: A comment stated that the AC-powered bone saw should be classified into class I because the risks to health identified by the Panel, i.e., the possibility of bone and tissue trauma and electrical shock, are not sufficient to warrant classification of the device into class II.

FDA disagrees with the comment. FDA believes that a performance standard is necessary for this device to assure that its design will not cause bone damage or tissue trauma. Accordingly, FDA believes that the proposed classification was correct and, therefore, is classifying the device into class II.

9. Comments on the proposed regulations classifying the devices listed below argued that the devices should be placed into class I because the agency identified no substantive risks to health associated with the devices that would justify classifying them into class II. The comments argued further that the biocompatibility concerns of the agency are unfounded and, therefore, that the statutory criteria for class II have not been met.

Section No.	Device	Class recommended by section	Class proposed by FDA
872.3310	Coating material for resin filings	II	II
872.3590	Preformed plastic denture tooth	II	II
872.3690	Tooth shade resin material	II	II
872.3750	Bracket adhesive resin and tooth conditioner	II	II
872.3760	Denture relining, repairing, or rebasing resin	II	II
872.3765	Pit and fissure sealant and conditioner	II	II
872.3770	Temporary crown and bridge resin	I	II
872.3820	Root canal filling resin	I	II
872.5470	Orthodontic plastic bracket	I	II

FDA disagrees with these comments. FDA believes that the biocompatibility and performance concerns discussed in the proposed regulations warrant classifying these devices into class II. There are numerous materials that may be used in these devices that could have an adverse effect on patients. For example, there are studies that describe the carcinogenic potential of certain materials that may be used to fabricate dental resins (Refs. 1 and 2). Because of the potentially serious risks that may be presented by exposure to various materials used in these devices, the agency believes that, except for a root canal filling resin containing chloroform, performance standards are necessary to provide reasonable assurance of the safety and effectiveness of these devices.

The agency has been informed that certain root canal filling resins in commercial distribution may contain chloroform as an ingredient. FDA believes that the safety and effectiveness of a root canal filling resin containing chloroform has not been established because chloroform may be a carcinogen. In the **Federal Register** of June 29, 1976 (41 FR 26842), FDA published a final rule declaring that any human drug or cosmetic product containing chloroform that is introduced or delivered for introduction in interstate commerce will be subject to regulatory action.

The agency believes that root canal filling resin containing chloroform presents a potential unreasonable risk of illness or injury because of possible carcinogenicity. Consequently, FDA now believes that premarket approval is necessary for root canal filling resin containing chloroform. FDA believes that general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of this device when it contains chloroform and that insufficient information exists to establish a standard to provide such assurance.

Accordingly, except for root canal filling resin containing chloroform, FDA believes that the proposed classifications of the devices above are correct and is classifying the devices into class II. FDA is classifying root canal filling resin into class II when chloroform is not used as an ingredient and is classifying this device into class III when it contains chloroform.

10. The only specific comments received on the proposed classifications of the devices listed below agreed with FDA's proposals to classify the devices into class II. The comments stated that implantation of these devices may have undesirable effects on patients if improper materials are used in the devices' composition.

Docket No.	Device
78N-2888	Titanium subperiosteal implant material.
78N-2889	Cobalt chrome molybdenum implant material.

FDA agrees with the comments. For the reasons provided in the proposed regulations, FDA is classifying these devices into class II (§ 872.3645).

11. Comments on the proposed classifications of the devices listed below argued that the devices should be classified into class I rather than class II as proposed. The comments suggested that if the identifications of these devices were limited to devices of the same composition as those are being marketed with demonstrated acceptable levels of safety and effectiveness, the general controls provided by class I would be sufficient to assure their safety and effectiveness. In that case, the comments reasoned, a manufacturer intending to market a new device of this type or a device of a different composition would be required to submit to FDA a premarket notification, and FDA could place that device into a

class other than class I if it determined that class I was not sufficient to assure its safety or effectiveness.

Docket No.	Device	Class recommended by section	Class proposed by FDA
78N-2844	Gold based alloy for clinical use	II	II
78N-2845	Precious metal alloy for clinical use	II	II
78N-2851	Precision attachment	I	II
78N-2852	Preformed bar	I	II
78N-2859	Preformed clasp	I	II
78N-2860	Preformed wire clasp	II	II
78N-2849	Preformed anchor	I	II
78N-2863	Preformed crown	I	II
78N-2864	Gold and stainless steel cusp	I	II
78N-2865	Preformed cusp	I	II
78N-2884	Preformed gold denture tooth	I	II
78N-2898	Retentive and splinting pin	I	II
78N-2904	Root canal post	I	II
78N-2910	Posterior artificial teeth with metal insert	I	II

The Panel had recommended that gold based alloy for clinical use and precious metal alloy for clinical use be placed in class II in order to prevent an adverse tissue reaction if the materials used in the devices are not biocompatible. FDA still agrees with the Panel's recommendations on these two devices and, therefore, is classifying them into class II as proposed.

With respect to the classification of the other devices listed above, FDA agrees with the comments recommending that the devices be classified into class I rather than class II. The agency believes that each of these devices has maintained an acceptable level of performance based on the compositional range of the materials now being used in the devices; i.e., austenitic alloys or alloys of 75 percent or greater content of gold and metals of the platinum group. Devices of such composition have been shown to be biocompatible, inert, sufficiently strong, and otherwise safe and effective when used in the mouth. Consequently, considering that FDA will learn of new compositions of material, through premarket notification under section 510(k) of the act (21 U.S.C. 360(k)), FDA agrees that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of these devices and that establishment of a performance standard for these devices is unnecessary. As suggested by the comments, FDA is changing the identification of each of these devices to state that the device is composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group.

12. Comments on the proposed regulations on the devices listed below argued that, because a performance standard administered by FDA under the Radiation Control for Health and Safety Act (42 U.S.C. 263f) already exists for each of these devices, establishing any additional performance standards under the amendments would be overregulation. The comments argued that the existing standards to which these devices are required to conform should be the sole standards for these devices.

Section	Device	Class recommended by section	Class proposed by FDA
872.1800	Extraoral source X-ray system	II	II
872.1810	Intraoral source X-ray system	II	II
872.1830	Cephalometer	II	II
872.1840	Dental X-ray position indicating device	II	II
872.1850	Lead-lined position indicator	II	II

When the only risk to health presented by a radiation-emitting device is adequately controlled by a standard under the Radiation Control and Safety Act, no other standard is needed to assure the safety and effectiveness of a medical device, and FDA will classify the device into class I. However, the devices listed above present risks to health other than those controlled by an existing standard. For example, unintended exposure to x-rays resulting from lack of effectiveness due to faulty design of the device may not be covered by an existing standard but may need to be controlled by a performance standard under section 514 of the act (21 U.S.C. 360d) to assure a device's safety and effectiveness. Accordingly, FDA is classifying each of the devices listed above into class II as proposed.

13. Comments on the proposed regulations classifying the devices listed below argued that these devices are raw materials used in the fabrication of custom devices and, therefore, should be exempt from sections 514 and 515 of the act (21 U.S.C. 360d and 360e) under the custom device exemption in section 520(b) of the act (21 U.S.C. 360j(b)). The comments further stated that none of these devices is intended for use by a patient until it is tailored by a trained professional to meet the individual needs of the patient.

Section	Device
872.1730	Electrode gel for pulp tester.
872.3050	Amalgam alloy.
872.3060	Gold based alloy for clinical use.
872.3250	Calcium hydroxide cavity liner
872.3260	Cavity varnish.
872.3275	Dental cement.

Section	Device
872.3300	Hydrophilic resin coating for dentures.
872.3310	Coating material for resin fillings.
872.3590	Preformed plastic denture tooth.
872.3660	Impression material.
872.3700	Dental mercury.
872.3710	Base metal alloy.
872.3750	Bracket adhesive resin and tooth conditioner.
872.3760	Denture relining, repairing, or rebasing resin.
872.3765	Pit and fissure sealant and conditioner.
872.3850	Gutta percha.
872.3920	Porcelain tooth.
872.5410	Orthodontic performed band.
872.6660	Porcelain powder for clinical use.
872.6890	Intraoral dental wax.

FDA disagrees with the comments. The devices listed above do not meet the requirements of the partial exemption for custom devices because (a) the devices need not necessarily deviate from an otherwise applicable performance standard or requirement prescribed by or under section 515 of the act, (b) the devices are generally available in finished form for purchase or for dispensing upon prescription, (c) the devices are offered for commercial distribution, and (d) the devices are generally available to or generally used by dentists. Thus, although these devices may be formed according to the needs of individual patients, the devices do not meet the requirements of section 520(b) of the act for an exemption from section 514 or 515.

14. Comments on the proposed regulations listed below argued that, in classifying these devices, both the Panel and FDA incorrectly used the criteria that were used by FDA's OTC Drug Review Panel in its review of these products when they were regarded as drugs. The comments argued that the criteria used for classifying devices should be different from those applied by the OTC Drug Review Panel. The comments also suggested that the devices be classified into class I, rather than class III as proposed, because of insufficient documentation that they present an actual risk to users.

Section	Device	Class recommended by section	Class proposed by FDA
872.3540	OTC denture cushion	III	III
872.3550	OTC denture pad	III	III
872.3560	OTC denture reliner	III	III
872.3570	OTC denture repair kit	III	III

FDA agrees in part and disagrees in part with the comments. FDA disagrees that the agency employed incorrect criteria when proposing to classify these devices. As stated in the proposals, the devices present a risk of illness or injury. Use of these devices may cause an improper vertical dimension of a denture which may result in increased biting forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The long-term irritation of oral tissue caused by an incorrect vertical dimension also could cause formation of carcinomas. FDA also disagees with the comments' assertion that FDA did not provide in the proposed regulations sufficient documentation of the health risks presented by these devices. FDA cited in the proposed regulations a summary report by the OTC Panel on Dentifrices and Dental Care Agents, May 22, 1978, showing the hazards presented by these devices (Ref. 6).

Section 872.3540; OTC denture cushion: During an open meeting of the Panel on March 12 and 13, 1979, a manufacturer presented the results of a study that showed that disposable OTC denture cushions made of wax-impregnated cotton cloth that the patient applies to the entire base of a denture before the patient inserts the denture into the mouth are safe and effective for short-term use (Ref. 7). The Panel believed that the data showed that this version of the OTC denture cushion is safe and effective; because a single layer of material is used to make the cushion, the disposable cushion is discarded after 1 day's use, and the device is intended for short-term use. Therefore, during that meeting, the Panel recommended that this version of the OTC denture cushion be classified into class I. Inadvertently, FDA did not reflect this portion of the Panel's recommendation in its proposed classifications of the OTC denture cushion and OTC denture pad. A summary of the Panel's recommendation is, however, in the administrative record for this rulemaking. FDA agrees with the recommendations of the Panel that the OTC denture cushion be classified into class I, provided that the device is made of wax-impregnated cotton cloth and is for the intended uses described above.

In the final rule, FDA has grouped the OTC denture cushion and the OTC denture pad into one generic type of device, the OTC denture cushion and pad (§ 872.3540).

Accordingly, in the final rule FDA is classifying into class I the OTC denture cushion and pad, if the device is made of wax-impregnated cotton cloth, if it is intended to be discarded after 1 day's use, and if it is intended for short-term use. FDA is classifying all other OTC denture cushions and pads, the OTC denture reliner, and the OTC denture repair kit into class III as proposed. FDA is classifying these devices into class III because these devices present potential unreasonable risks of illness or injury as described above and in the proposals, and because general controls or performance standards are insufficient to provide reasonable assurance of their safety and effectiveness.

15. Comments on the proposed regulations classifying the denture adhesives listed below said that these devices should not be identified by the names of the ingredients in them. The comments said that, by listing the specific ingredients or precentages of ingredients in the names of these devices and in their identifications, FDA is inhibiting formula improvements by subjecting denture adhesives containing different ingredients or different percentages of ingredients to extensive compliance requirements, such as submission of premarket notification and petitions for reclassification.

Docket No.	Device
78N-2866	Acacia and Karaya with sodium borate denture adhesive.
78N-2867	Carboxymethylcellulose sodium (40 to 100 percent) denture adhesive.
78N-2868	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.
78N-2869	Carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive.
78N-2870	Carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesive.
78N-2871	Karaya denture adhesive.
78N-2872	Karaya and ehylene oxide homopolymer denture adhesive.

Docket No.	Device
78N-2873	Karaya with sodium borate denture adhesive.
78N-2874	Polyacrylamide polymer (modified cationic) denture adhesive.
78N-2875	Polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.
78N-2876	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer and carboxymethyl-cellulose sodium (NACMC) denture adhesive.
78N-2877	Polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethyl-cellulose sodium denture adhesive.

FDA agrees in part and disagrees in part with the comments. FDA agrees that, for certain of the denture adhesives, it is unnecessary to identify the percentages of ingredients. Accordingly, in the final rule, the percentages of ingredients have been removed where possible. However, FDA believes that for certain denture adhesives, it is necessary to identify in the names of the devices and their identifications the ingredients and, for some, the percentages of the ingredients, for accurate identification of denture adhesives in commercial distibution when the device amendments were enacted. Manufacturers who intend to significantly change the formula of a commercially distributed denture adhesive are subject to a requirement of premarket notification (see § 872.3(b) of this rule).

16. Docket No. 78N-2866; Acacia and karaya with sodium borate denture adhesive; proposed class III—Docket No. 78N-2873; Karaya with sodium borate denture adhesive; proposed class III: One comment on the proposed regulations classifying these two devices argued that they have been used for a number of years with no evidence of adverse effects and recommended that the devices be classified into class I rather than class III as proposed.

FDA agrees that the devices have been used for years without reports of adverse effects. The Panel based its original recommendations, and FDA based its original proposed classifications of the two devices, on a report of an advisory committee of FDA's Bureau of Drugs (now the Center for Drugs and Biologics), the OTC Panel on Dentifrices and Dental Care Agents (Ref. 6). The report showed a lack of data concerning the safety and effectiveness of denture adhesives composed of acacia and karaya with sodium borate when the sodium borate concentration in the product ranged from 12 to 20 percent by weight. During a meeting of the Panel on March 12 and 13, 1979, another study was presented showing that a denture adhesive containing less than 12 percent by weight sodium borate is safe and effective when the device is used correctly (Ref. 3)., Following review of that presentation, the Panel recommended that the two devices be classified into class II instead of class III, because it believed that premarket approval of the devices was unnecessary. The Panel also believed that establishment of performance standards was necessary to control the level of sodium borate in the devices to ensure that this level does not exceed 12 percent by weight. Inadvertently, FDA did not incude the more recent recommendations of the Panel in the proposed classifications of the two devices. A summary of the Panel's recommendations is, however, in the administrative record for this rulemaking.

Following review of all of the information on the two devices now available, FDA is classifying into class I both the acacia and karaya with sodium borate denture adhesive and the karaya with sodium borate denture adhesive, when the level of sodium borate by weight is less than 12 percent. FDA now believes that the general controls of class I will provide reasonable assurance of the safety and effectiveness of the two devices when the level of sodium borate is less than 12 percent and that performance standards and premarket approval are unnecessary.

Because no data are available to establish the highest level of sodium borate in a denture adhesive that is safe, the agency believes that acacia and/or karaya denture adhesives with sodium borate content by weight of 12 percent or more should be classified into class III. These devices are purported or represented to be for a use (restoring dental function by affixing dentures to the gums) which is of substantial importance in preventing impairment of human health. Because long-term use of the devices may cause toxicity in the patient, the agency believes that the devices present a potential unreasonable risk of illness or injury. Premarket approval is necessary for the devices because general controls and performance standards are insufficient to provide reasonable assurance of their safety and effectiveness. Moreover, insufficient information exists to establish standards to provide such assurance. Accordingly, FDA is classifying the devices into class I when they contain less than 12 percent by weight sodium borate and into class III when they contain 12 percent or more by weight sodium borate.

17. Section 872.3640; Endosseous implant; proposed class III: One comment on the endosseous implant supported FDA's proposed classification of the device into class III, noting that the state-of-the-art is not sufficiently advanced to allow standards to be written that would provide reasonable assurance of the safety and effectiveness of the materials used in this implant.

FDA agrees that premarket approval is necessary to assure the safety and effectiveness of this device. FDA is classifying the device into class III as proposed.

18. Section 872.3890; Endodontic stabilizing splint; proposed class II: One comment on the proposed classfication of endodontic stabilizing splints argued that the device should be classified into class I because it has been used for many years with no reported problems and because the agency cited no adverse experience reports or complaint data to support classifying it into class II.

FDA disagrees with the comment. FDA believes that the risks to health identified in the proposed regulation for this device support classifying it into class II. The device is intended to be implanted into the root canal of a tooth and to extend beyond the apex of the tooth into the alveolar bone. Thus, the device comes into direct contact with a tooth, the periodontal membrane, and the bone and, therefore, may cause an adverse tissue reaction if it is not biocompatible. In addition, device breakage due to the use of faulty materials in the construction of the device could cause unnecessary trauma or loss of a tooth. Accordingly, FDA is classifying the endodontic stabilizing splint into class II as proposed.

19. Section 872.3920; Porcelain tooth; proposed class II—§ 872.6660; Porcelain powder for clinical use; proposed class II:

19a. Some comments on the proposed classifications of porcelain teeth and porcelain powder for clinical use (used to make procelain teeth) agreed that these devices should be classified into class II as proposed, because the amount of depleted uranium that is used in these devices to provide fluorescing characteristics should be controlled by a standard.

FDA agrees with the comments. During 1976, FDA collected samples and

tested porcelain teeth and porcelain powder for clinical use for levels of depleted uranium in the devices and levels of ionizing radiation emitting from them (Ref. 8). The agency found that U.S. manufacturers of these devices limit levels of depleted uranium in the devices to 300 parts per million, tye voluntary standard limit set by domestic manufacturers. Some foreign manufacturers of these devices, however, use levels of depleted uranium as high as 1,000 parts per million. Although there is no evidence that levels of depleted uranium of 300 parts per million, or less, are unsafe, FDA has suggested that manufacturers develop suitable substitute materials to provide fluorescing characteristics to replace depletion uranium. FDA believes that when these devices contain levels of depleted uranium greater than 300 parts per million, the devices present increased risks from ionizing radiation. Accordingly, FDA believes that performance standards are necessary to control the levels of depleted uranium in the devices and the levels of ionizing radiation emitted from them in order to provide reasonable assurance of their safety and effectiveness. FDA believes that the general controls of class I alone are insufficient to provide reasonable assurance of the safety and effectiveness of these devices.

19b. Some comments on the proposed classification of porcelain teeth stated that the device should be placed in class I instead of class II as proposed, because no legitimate risks to health justifying classification of the device into class II were identified in the proposed regulation. Other comments stated that there are no known risks to health from the device that can be regulated by a standard.

FDA disagrees with the comments. In the proposed regulations, FDA identified the risks to health presented by ionizing radiation emitted from radioactive material that may be present in the device. As stated above, FDA believes that these risks, can be regulated by a performance standard.

19c. Some comments on the proposed regulation classifying porcelain teeth also said that manufacturers have voluntarily limited the uranium content of the device to 300 parts per million and that, therefore, no mandatory standard is necessary.

FDA believes that a mandatory performance standard is needed to control the levels of ionizing radiation emitted by the devices. Accordingly, FDA is classifying porcelain teeth and porcelain powder for clinical use into class II as proposed.

20. Section 872.4600; Intraoral ligature and wire lock; proposed class II: A comment on the proposed classification of the intraoral ligature and wire lock stated that the device should be placed in class I rather than class II as proposed, because the risk to health presented by the device, i.e., reopening of the bone fracture if the lock breaks, could be controlled adequately by the general controls applicable to class I devices.

FDA disagrees with the comment. In the proposed regulation, FDA identified the risks to health presented by the device as infection if the device cannot be sterilized properly, reopening of the fracture if the lock breaks, and adverse tissue reaction if the materials used in the device are not biocompatible. FDA believes that the general controls of class I are insufficient to control the design of the device to assure that it can be sterilized properly, to assure that it has sufficient strength, and to assure that the materials used in it are biocompatible. Because the device is an implant that is intended to be placed in the body for an indefinite period, it is critical that these aspects of the device be adequately controlled. Accordingly, FDA is classifying the device into class II as proposed.

21. Section 872.4730; Dental injecting needle; proposed class II: A comment on the proposed classification of this device stated that it should be placed in class I rather than class II as proposed because the risk to health presented by the device, i.e., the possibility of tissue damage if needles are not sharp or straight, is not sufficient to warrant classifying the device into class II.

FDA now believes that the dental injecting needle should be classified into class I. FDA proposed to classify the device into class II because of concerns about tissue trauma if the device is constructed of inferior materials or if the device has a defective point, and possible adverse tissue reactions if the materials used in the device are not biocompatible. FDA now believes that the risk to health of patients presented by dental injecting needles that may be made of inferior materials or have defective points are minimal, and that these risks would be controlled by manufacturers' adherence to the CGMP regulations. FDA believes it is unnecessary to establish performance standards for the device to control the risk of tissue trauma. FDA now believes that in 1980, when it proposed to classify the device, the agency assigned to the device a higher level of risk of bioincompatibility than was justified by the years of experience of dentist and patients with the device. Thus, FDA now believes that it is unnecessary to establish a performance standard for the dental injecting needle to control the risk of bioincompatibility, because FDA believes that the device presents only minimal risks and that these minimal risks would not be significantly reduced through establishing performance standards for the device due to the idiosyncratic nature of individual sensitivities. The labeling of a device that cause sensitivity reactions in some individual should be so labeled to be in compliance with the misbranding provisions (21 U.S.C. 352) of the general controls of the act. FDA now believes that the general controls of class I, particularly the controls of the CGMP regulation in Part 820, would provide reasonable assurance of the safety and effectiveness of the dental injecting needle. Accordingly, FDA is classifying the device into class I.

22. Section 872.4760; Bone plate; proposed class II: A comment on the proposed classification of this device suggested that the bone plate be classified into class I instead of class II as proposed because the risk to health presented by the device, i.e., reopening of a bone fracture due to faulty construction, cannot be controlled by a performance standard.

FDA disagrees with the comment. In the proposed regulation, FDA identified the risks to health presented by the device as infection if the device cannot be sterilized properly, bone damage if the device is constructed improperly, and adverse tissue reaction if the materials used in the device are not biocompatible. The agency also noted that the device is an implant because it is intended to be placed into the body for an indefinite period. FDA believes that the general controls of class I are insufficient to control the design of the device to assure that it can be sterilized properly, to assure that it has sufficient strength, to assure that it is constructed so as to avoid bone damage, and to assure that it is constructed of materials that are biocompatible. Accordingly, FDA is classifying the device into class II as proposed.

23. Section 872. 4840; Rotary scaler; proposed class II: A comment on the proposed regulation stated that the device should be placed in class I rather than class II as proposed because the risk to health presented by the device, i.e., the possibility of damage to tooth enamel or dental pulp caused by scouring action and heat, is insufficient to warrant classifying the device into class II. The comment added that no

standard can ensure the user's skill and judgment in using the device.

FDA disagrees with the comment. The device is intended to remove calculus deposits from teeth, using a combination of mechanical vibration, abrasive, action, and pressure, without causing damage to tooth enamel or dental pulp. Although the dentist or dental hygienist controls the pressure applied, the vibration and scouring action results from the design of the device. Therefore, FDA believes that a performance standard is necessary to control the design of the surfaces of the device that are intended to remove the calculus deposits from the teeth in order to ensure that the teeth are not damaged and that the device is effective. Accordingly, FDA is classifying the device into class II as proposed.

24. Section 872.4920; Dental electrosurgical unit and accessories; proposed class II: Two comments agreed with FDA's proposed classification of this device into class II. One of the comments suggested that the American National Standards Institute/American Dental Association Specification Number 44 be reviewed to determine its propriety for adoption as a performance standard for the device.

FDA agrees with the comments regarding classification of the electrosurgical unit and accessories. Accordinly, FDA is classifying the device into class II as proposed. The existence of a voluntary standard for a device is one of the factors FDA considers in setting its priorities for establishing a performance standard for a device classified into class II. See "B. FDA's Priorities for Establishing Performance Standards." When FDA initiates proceedings to establish a performance standard for the electrosurgical unit and accessories under section 514(c)(1) of the act, FDA will publish in the **Federal Register** a notice inviting any person to submit an existing standard or an offer to develop a standard for the device. If a person submits the voluntary standard above in response to such a notice accompanied by the information specified in section 514(c)(3) of the act, FDA would consider acceptance of such an existing standard as the performance standard, as provided in section 514(d)(1)(A) of the act.

25. Section 872.5500; Extraoral orthodontic headgear; proposed class II: A comment on the proposed regulation stated that extraoral orthodontic headgear should be classified into class I rather than class II as proposed, because the agency cited no adverse experience reports involving this device. The comments said the device has been used satisfactorily for many years.

FDA disagrees with the comment. The agency has received adverse experience reports showing that use of the extraoral orthodontic headgear can cause serious injuries in young children. The facebow, when pulled out of the molar tubes, can spring back into the mouth or face of the wearer. One patient suffered irreparable injury to both eyes when the patient's sister pulled the facebow and let go of it (Ref. 4). The agency believes that the risk of this type of injury would be reduced by a performance standard that includes the requirement that a disengaging mechanism for the headgear be incorporated in the design of the device. For this reason, and for the other reasons given in the proposed regulation, FDA is classifying the device into class II as proposed.

26. Section 872.6080; Airbrush; proposed class III: A comment on the proposed regulation stated that the airbrush is not intended for dental purposes and, therefore, should not be included in the group of dental devices being classified.

As stated in the preamble to the proposed general provisions (45 FR 85965) under the heading "Products That Have Both Medical and Nonmedical Uses," FDA will regulate a product as a medical device if it is intended for a medical purpose. FDA believes that the airbrush, which is intended for use in roughening the surfaces of dental restorations in order to detect uneven areas, is intended for a medical purpose. Accordingly, FDA is classifying the device into class III as proposed.

27. Section 872.6730; Endodontic dry heat sterilizer; proposed class III: A comment on the proposed regulation suggested that the device be classified into class II instead of class III as proposed, arguing that a performance standard would ensure that the device sterilizes instruments satisfactorily, i.e., that the heat generated is adequate and evenly distributed throughout the sterilizing chamber of the device.

FDA disagrees with the comment. The studies cited in the proposed regulation raise questions concerning the effectiveness of the endodontic dry heat sterilizer. The studies indicate that the device may not sterilize instruments satisfactorily, even when the device reaches and maintains the temperature it is intended to reach. Thus, FDA believes that insufficient information exists to determine that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is classifying the device into class III as proposed.

28. Section 872.6770; Cartridge syringe; proposed class II: One comment on the proposed regulation stated that the cartridge syringe should be classified into class I rather than class II as proposed because the agency identified no risks to health presented by the device that could not be controlled by the general controls applicable to class I devices.

FDA disagrees with the comment. The agency believes that a performance standard is necessary to ensure that cartridge syringes aspirate properly to prevent injection of drugs directly into the blood vessels of patients. Accordingly, FDA is classifying the device into class II as proposed

I. Exemptions for Class I Devices

29. FDA received many general comments on the proposed classification regulations requesting the agency to grant all exemptions recommended by the Panel. Other comments requested exemptions for specific class I devices only.

29a. Exemptions from CGMP regulations. In response to comments recommending that all class I devices be exempted from the CGMP regulations, FDA is granting certain exemptions for some class I dental devices.

FDA is exempting manufacturers of 19 of the 57 class I dental devices from the CGMP regulations with respect to their manufacture of these devices, with the exception of the requirements specified in 21 CFR 820.180 and 820.198 relating to records and complaint files. As stated in the proposed regulations, 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 followup. 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. The agency announced the availability of these guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671). The guidelines assist petitioners in complying with the provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). Section 513(d)(2)(A) of the act allows FDA to approve an exemption for a device from a requirement if the agency determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with the act.

29b. Exemptions from requirement of premarket notification. Many comments requested that exemptions from premarket notification procedures in section 510(k) of the act and Subpart E of 21 CFR Part 807 be granted for all class I dental devices.

In this final rule, FDA is granting an exemption from the requirement of premarket notification only for the pantograph (§ 872.3730), one of 12 dental devices for which such exemptions were proposed. The remaining 11 devices have been grouped with various other dental devices for which FDA did not propose such exemptions. Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant exemptions from premarket notification for 23 class I dental devices, including the 11 devices for which FDA proposed an exemption for premarket notification.

J. 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 System Devices Panel.	March 9, 1979, 44 FR 13284-13434 (proposals); February 5, 1980, 45 FR 7904-7921 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel.	February 2, 1982, 47 FR 4802-4829 (proposals).
Hematology and Pathology Devises 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, 44 FR 49645-49954 (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 53012-53029 (final regulations).
Immunology Devices Panel.	April 22, 1980, 45 FR 27204-27359 (proposals); November 9, 1982, 47 FR 50614-50840 (final regulations).
Microbiology Devices Panel.	Do.
Obstetrics-Gynecology Devices Panel.	April 3, 1979, 44 FR 19694-19971 (proposals); February 26, 1980, 45 FR 12682-12710 (final regulations).
Radiologic Devices Panel.	January 29, 1982, 47 FR 4496-4451 (proposals).
Ophthalmic Devices Panel.	January 26, 1972, 47 FR 3694-3749 (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); August 12, 1987 (final regulations).
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 51726-51779 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices).	August 28, 1979, 44 FR 50459-50537 (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).

K. Codification of Two Devices not Subjects of Dental Proposed Regulations

Statutory Classification of Tricalcium Phosphate Granules for Dental Bone Repair. The amendments include transitional provisions applicable to devices intended for human use that were considered to be new drugs before enactment of the amendments (see section 520(l)(1)(E) of the act (21 U.S.C. 360j(l)(1)(E)). The transitional provisions assure that devices formerly considered as new drugs continue to be subject to appropriate regulatory controls as the amendments are being implemented. Thus, a device previously considered a new drug is classified into class III unless the agency in response to a petition has reclassified it into class I or class II. FDA is including in this final rule (§ 872.3930) a section codifying and statutory classification into class III of a commercially distributed, transitional dental device, tricalcium phosphate granules for dental bone repair. A previous **Federal Register** notice published on December 16, 1977 (42 FR 63474) described the regulatory status of this product.

Reclassification of the Caries Detection Device. A postamendments device that is not substantially equivalent to devices marketed before the amendments is classified by statute into class III by section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). In response to a petition under section 513(f)(2) of the act and 21 CFR Part 860 of the regulations, FDA may reclassify such a new device into class I or class II.

On September 27, 1979, FDA received a petition (Docket No. 80P-0064) requesting the agency to reclassify the caries detection device from class III to class II. In the **Federal Register** of May 2, 1980 (45 FR 29411), FDA published the recommendation of the Panel that the device be reclassified from class III to class II. The agency provided a period of 30 days for interested persons to submit written comments on the recommendation. No comments were received. FDA agreed with the Panel's recommendation that the device be reclassified. In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA approved the petition and, by order in the form of a letter to the petitioner dated November 18, 1982, reclassified the device from class III to class II.

FDA is codifying the reclassification of the caries detection device reclassified into class II in § 872.1740. The order and the regulation apply to any detection 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.

L. Minor Changes or Clarifications

Occasionally the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. The agency also is adding paragraphs in § 872.1 *Scope* to explain (1) that references in Part 872 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted; and (2) that a device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only. The agency also is adding new § 872.3 *Effective dates of requirements for premarket approval* to explain the various effective dates for premarket approval requirements for devices classified into class III and explain why FDA also is adding new paragraph (c) in the classification regulation for each device classified into class III to declare, where applicable, the effective date for premarket approval requirements for the device.

M. 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.

1. Athas, W. F., et. al., "In Vitro Studies on the Carcinogenic Potential of Orthodontic Bonding Material," *Ecotoxicology and Environmental Safety*, 3:401-410, 1979.

2. Hine, C. H., et. al., "An Investigation of the Oncogenic Activity of Two Representative Epoxy Resins," *Cancer Research*, 18:20-26, 1958.

3. Cohen, Albert, "The Determinations of Plasma and Urinary Excretion Levels of Boron in Volunteers Using Rigident® Denture Retainer on a Twice Daily Basis for Sixty (60) Days," July 18, 1979 (unpublished). Presentation made to the Dental Devices Advisory Panel during a meeting of March 12 and 13, 1979.

4. Summary of adverse experiences with extraoral orthodontic headgear reported to FDA.

5. Summary of adverse experiences with liquid-filled teething rings and other data reported to FDA.

6. Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978. Presentation to the FDA Dental Devices Advisory Panel by the WJK Corporation on EZO Denture Cushions, March 12, 1979.

8. Thompson, D. L., "Uranium in Dental Porcelain," U.S. Dept HEW, FDA, Bureau of Radiological Health, Rockville, MD 20852, HEW Publication (FDA) 76-8061, September 1976.

9. Thompson, J., and J. A. Russell, "Dermatitis Due to Mercury Following Amalgam Dental Restorations," *British Journal of Dermatology*, 82:292, 1970.

10. Shovelton, D. S., "Silver Amalgam and Mercury Allergy," *Oral Surgery, Oral Medicine, and Oral Pathology*, January 1968.

11. Juhlin, L., and S. Ohman, "Allergic Reactions to Mercury in Red Tattoos and in Mucosa Adjacent to Amalgam Fillings," *Acta Dermato Venereologica*, 48:103-105, 1968.

12. Matrix prepared by FDA showing its decisions on the 185 dental device classification proposed regulations.

N. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

O. Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined 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 the 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 1(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 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. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact and are not major rules.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued before January 1, 1981, and, therefore, is exempt. In any event, the rule would not have a significant economic effect on a substantial number of small entities.

List of Subjects in 21 CFR Part 872

Dental 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 872, to read as follows:

PART 872—DENTAL DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Sec.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

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

§ 872.1 Scope.

(a) This part sets forth the classification of dental 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 by § 807.87.

(c) To avoid duplicative listings, a dental device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

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

§ 872.3 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 paragraphs (b) and (c) 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.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional 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—Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) *Identification.* A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(b) *Classification.* Class I.

§ 872.1720 Pulp tester.

(a) *Identification.* A pulp tester is an AC or battery powered device intended

to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.

(b) *Classification.* Class II.

§ 872.1730 Electrode gel for pulp testers.

(a) *Identification.* An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current

(b) *Classification.* Class I.

§ 872.1740 Caries detection device.

(a) *Identification.* The caries detection device is a device intended to show the existence of decay in a patient's tooth by use of electrical current.

(b) *Classification.* Class II.

§ 872.1800 Extraoral source X-ray system.

(a) *Identification.* An extraoral source X-ray system is an AC-powered device that produces X-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification.* Class II.

§ 872.1810 Intraoral source X-ray system.

(a) *Identification.* An intraoral source X-ray system is an electrically powered device that produces X-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification.* Class II.

§ 872.1820 Dental X-ray exposure alignment device.

(a) *Identification.* A dental X-ray exposure alignment device is a device intended to position X-ray film and to align the examination site with the X-ray beam.

(b) *Classification.* Class I.

§ 872.1830 Cephalometer.

(a) *Identification.* A cephalometer is a device used in dentistry during X-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental X-rays.

(b) *Classification.* Class II.

§ 872.1840 Dental X-ray position indicating device.

(a) *Identification.* A dental X-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the X-ray beam and to restrict the dimensions of the dental X-ray field by limiting the size of the primary X-ray beam.

(b) *Classification.* Class II.

§ 872.1850 Lead-lined position indicator.

(a) *Identification.* A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental X-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the X-rays by absorbing divergent radiation, and to prevent leakage of radiation.

(b) *Classification.* Class II.

§ 872.1905 Dental X-ray film holder.

(a) *Identification.* A dental X-ray film holder is a device intended to position and to hold X-ray film inside the mouth.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

§ 872.3050 Amalgam alloy.

(a) *Identification.* An amalgam alloy is a device that consists of a metallic substance intended to be mixed with mercury to form filling material for treatment of dental caries.

(b) *Classification.* Class II.

§ 872.3060 Gold-based alloys and precious metal alloys for clinical use.

(a) *Identification.* Gold-based alloys and precious metal alloys for clinical use are mixtures of metals, the major components of which are gold, silver, or palladium. They also may contain a small quantity of copper or platinum. The device is intended to fabricate dental appliances, such as crowns and bridges, for patients.

(b) *Classification.* Class II

§ 872.3080 Mercury and alloy dispenser.

(a) *Identification.* A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.

(b) *Classification.* Class I.

§ 872.3110 Dental Amalgam capsule.

(a) *Identification.* A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.

(b) *Classification.* Class I.

§ 872.3130 Preformed anchor.

(a) *Identification.* A preformed anchor is a device made of austenitic alloys or alloys containing 75 percent or greater gold or metals of the platinum group intended to be incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient's mouth.

(b) *Classification.* Class I.

§ 872.3140 Resin applicator.

(a) *Identification.* A resin applicator is a brushlike device intended for use in spreading dental resin on a tooth during application of tooth shade material.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.3150 Articulator.

(a) *Identification.* An articulator is a mechanical device intended to simulate movements of a patient's upper and lower jaws. Plaster casts of the patient's teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient's jaws. An articulator is intended to fit dentures or provide orthodontic treatment.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.3165 Precision attachment.

(a) *Identification.* A precision attachment or preformed bar is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use in prosthetic dentistry in conjunction with removable partial dentures. Various forms of the device are intended to connect a lower partial denture with another lower partial denture, to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a

crown, or to connect a fixed bridge to a partial denture.

(b) *Classification.* Class I.

§ 872.3200 Resin tooth bonding agent.

(a) *Identification.* A resin tooth bonding agent is a device material, such as methylmethacrylate, intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.

(b) *Classification.* Class II.

§ 872.3220 Facebow.

(a) *Identification.* A facebow is a device intended for use in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is intended for use in placing denture casts accurately into an articulator (§ 872.3150) and thereby aiding correct placement of artificial teeth into a denture base.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.3240 Dental bur.

(a) *Identification.* A dental bur is a rotary cutting device made from carbon steel or tungsten carbide intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.

(b) *Classification.* Class I.

§ 872.3250 Calcium hydroxide cavity liner.

(a) *Identification.* A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.

(b) *Classification.* Class II.

§ 872.3260 Cavity varnish.

(a) *Identification.* Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

(b) *Classification.* Class II.

§ 872.3275 Dental cement.

(a) *Zinc oxide-eugenol*—(1) *Identification.* Zinc oxide-eugenol is a device composed of zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

(2) *Classification.* Class I.

(b) *Dental cement other than zinc oxide-eugenol*—(1) *Identification.* Dental cement other than zinc oxide-eugenol is a device composed of various materials other than zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.

(2) *Classification.* Class II.

§ 872.3285 Preformed clasp.

(a) *Identification.* A preformed clasp or a preformed wire clasp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient's mouth by fastening the appliance to an adjacent tooth.

(b) *Classification.* Class I.

§ 872.3300 Hydrophilic resin coating for dentures.

(a) *Identification.* A hydrophilic resin coating for dentures is a device that consists of a water-retaining polymer that is intended to be applied to the base of a denture before the denture is inserted into the patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class II.

§ 872.3310 Coating material for resin fillings.

(a) *Identification.* A coating material for resin fillings is a device intended to be applied to the surface of a restorative resin dental filling to attain a smooth, glaze-like finish on the surface of the filling.

(b) *Classification.* Class II.

§ 872.3330 Preformed crown.

(a) *Identification.* A preformed crown is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is intended for use as a functional restoration until a permanent crown is constructed. The device also may be intended for use as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.

(b) *Classification.* Class I.

§ 872.3350 Gold or stainless steel cusp.

(a) *Identification.* A gold or stainless steel cusp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group or stainless steel intended to provide a permanent cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) between the teeth and a removable denture.

(b) *Classification.* Class I.

§ 872.3360 Preformed cusp.

(a) *Identification.* A performed cusp is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) before permanent restoration of a tooth.

(b) *Classification.* Class I.

§ 872.3400 Karaya and sodium borate with or without acacia denture adhesive.

(a) *Identification.* A karaya and sodium borate with or without acacia denture adhesive is a device composed of karaya and sodium borate with or without acacia intended to be applied to the base of a denture before the denture is inserted into patient's mouth to improve denture retention and comfort.

(b) *Classification.* (1) Class I if the device contains less than 12 percent by weight of sodium borate.

(2) Class III if the device contains 12 percent or more by weight of sodium borate.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval of the device described in paragraph (b)(2). See § 872.3.

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

(a) *Identification.* An ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive is a device containing ethylene oxide homopolymer and/or carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class I.

§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

(a) *Identification.* A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

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

(a) *Identification.* Ethylene oxide homopolymer and/or karaya denture adhesive is a device composed of ethylene oxide homopolymer and/or karaya intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class I.

§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

(a) *Identification.* A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

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

(a) *Identification.* A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class I.

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

(a) *Identification.* Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3520 OTC denture cleanser.

(a) *Identification.* An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

(b) *Classification.* Class I.

§ 872.3540 OTC denture cushion or pad.

(a) *Identification.* An OTC denture cushion or pad is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter.

(b) *Classification.* (1) Class I if the OTC denture cushion or pad is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day's use.

(2) Class III if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b) of this section.

(c) *Data PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval of the device described in paragraph (b)(2). See § 872.3.

§ 872.3560 OTC denture reliner.

(a) *Identification.* An OTC denture reliner is a device consisting of a material such as plastic resin that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is intended to replace a worn denture lining and may be available for purchase over the counter.

(b) *Classification.* Class III.

(c) *Data PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3570 OTC denture repair kit.

(a) *Identification.* An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may be available for purchase over-the counter.

(b) *Classification.* Class III.

(c) *Data PMA or notice of completion of PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3580 Preformed gold denture tooth.

(a) *Identification.* A preformed gold denture tooth is a device composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use as a tooth or a portion of a tooth in a fixed or removable partial denture.

(b) *Classification.* Class I.

§ 872.3590 Preformed plastic dentue tooth.

(a) *Identification.* A preformed plastic denture tooth is a prefabricated device composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

(b) *Classification.* Class II.

§ 872.3600 Partially fabricated denture kit.

(a) *Identification.* A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.

(b) *Classification.* Class III.

(c) *Data PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3640 Endosseous implant.

(a) *Identification.* An endosseous implant is a device made of a material such as titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as

artificial teeth, and to restore the patient's chewing function.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3645 Subperiosteal implant material.

(a) *Identification.* Subperiosteal implant material is a device composed of titanium or cobalt chrome molybdenum intended to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for prostheses, such as dentures.

(b) *Classification.* Class II.

§ 872.3660 Impression material.

(a) *Identification.* Impression material is a device composed of materials such as alginate or polysulfide intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

(b) *Classification.* Class II.

§ 872.3670 Resin impression tray material.

(a) *Identification.* Resin impression tray material is a device intended for use in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray for use in cases in which a preformed impression tray is not suitable, such as the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.3680 Polytetrafluoroethylene (PTFE) vitreous carbon materials.

(a) *Identification.* Polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon intended for use in maxillofacial alveolar ridge augmentation (building up the upper or lower jaw area that contains the sockets in which teeth are rooted) or intended to cost metal surgical implants to be placed in the alveoli (sockets in which the teeth are rooted) or the temporomandibular joints (the joint between the upper and lower jaws).

(b) *Classification.* Class II.

§ 872.3690 Tooth shade resin material.

(a) *Identification.* Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth.

(b) *Classification.* Class II.

§ 872.3700 Dental mercury.

(a) *Identification.* Dental mercury is a device composed of mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or a broken tooth.

(b) *Classification.* Class I.

§ 872.3710 Base metal alloy.

(a) *Identification.* A base metal alloy is a device composed of a material, such as a mixture of nickel and chromium, intended for use in fabrication of a custom-made dental device, such as porcelain veneer for a tooth.

(b) *Classification.* Class II.

§ 872.3730 Pantograph.

(a) *Identification.* A pantograph is a device intended to be attached to a patient's head to duplicate lower jaw movements to aid in construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient's mouth opens, the pen records on graph paper the angle between the upper and the lower jaw.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.3740 Retentive and splinting pin.

(a) *Identification.* A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.

(b) *Classification.* Class I.

§ 872.3750 Bracket adhesive resin and tooth conditioner.

(a) *Identification.* A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound, such as polymethylmethacrylate, intended to cement an orthodontic bracket to a tooth surface.

(b) *Classification.* Class II.

§ 872.3760 Denture relining, repairing, or rebasing resin.

(a) *Identification.* A denture relining, repairing, or rebasing resin is a device composed of materials such as methylmethacrylate, intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

(b) *Classification.* Class II.

§ 872.3765 Pit and fissure sealant and conditioner.

(a) *Identification.* A pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, intended for use primarily in young children to seal pit and fissure depressions (faults in the enamel) in the biting surfaces of teeth to prevent cavities.

(b) *Classification.* Class II.

§ 872.3770 Temporary crown and bridge resin.

(a) *Identification.* A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.

(b) *Classification.* Class II.

§ 872.3810 Root canal post.

(a) *Identification.* A root canal post is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be cemented into the root canal of a tooth to stabilize and support a restoration.

(b) *Classification.* Class I.

§ 872.3820 Root canal filling resin.

(a) *Identification.* A root canal filling resin is a device composed of material, such as methylmethacrylate, intended for use during endodontic therapy to fill the root canal of a tooth.

(b) *Classification.* (1) Class II if chloroform is not used as an ingredient in the device.

(2) Class III if chloroform is used as an ingredient in the device.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval of the device described in paragraph (b)(2). See § 872.3.

§ 872.3830 Endodontic paper point.

(a) *Identification.* An endodontic paper point is a device made of paper intended for use during endodontic therapy to dry, or apply medication to, the root canal of a tooth.

(b) *Classification.* Class I.

§ 872.3840 Endodontic silver point.

(a) *Identification.* An endodontic silver point is a device made of silver intended for use during endodontic therapy to fill permanently the root canal of a tooth.

(b) *Classification.* Class I.

§ 872.3850 Gutta percha.

(a) *Identification.* Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

(b) *Classification.* Class I.

§ 872.3890 Endodontic stabilizing splint.

(a) *Identification.* An endodontic stabilizing splint is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.

(b) *Classification.* Class II.

§ 872.3900 Posterior artificial tooth with a metal insert.

(a) *Identification.* A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).

(b) *Classification.* Class I.

§ 872.3910 Backing and facing for an artificial tooth.

(a) *Identification.* A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

(b) *Classification.* Class I.

§ 872.3920 Porcelain tooth.

(a) *Identification.* A porcelain tooth is a prefabricated device made of porcelain powder for clinical use (§ 872.6660) intended for use in construction of fixed or removable prostheses, such as crowns and partial dentures.

(b) *Classification.* Class II.

§ 872.3930 Tricalcium phosphate granules for dental bone repair.

(a) *Identification.* Tricalcium phosphate granules for dental bone repair is a device intended to be implanted into the upper or lower jaw to provide support for prosthetic devices.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 872.3.

Subpart E—Surgical Devices

§ 872.4120 Bone cutting instrument and accessories.

(a) *Identification.* A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw.

(b) *Classification.* Class II.

§ 872.4130 Intraoral dental drill.

(a) *Identification.* An intraoral dental drill is a rotary device intended to be attached to a dental handpiece to drill holes in teeth to secure cast or preformed pins to retain operative dental appliances.

(b) *Classification.* Class I.

§ 872.4465 Gas-powered jet injector.

(a) *Identification.* A gas-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II.

§ 872.4475 Spring-powered jet injector.

(a) *Identification.* A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II.

§ 872.4535 Dental diamond instrument.

(a) *Identification.* A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth.

(b) *Classification.* Class I.

§ 872.4565 Dental hand instrument.

(a) *Identification.* A dental hand instrument is a hand-held device intended to perform various tasks in general dentistry and oral surgery procedures. The device includes the operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative amalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operative explorer surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative margin finishing periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, surgical osteotome chisel, endodontic broach, dental wax carver, endodontic pulp canal file, hand instrument for calculus removal, dental depth gauge instrument, plastic dental filling instrument, dental instrument handle, surgical tissue scissors, mouth mirror, orthodontic band driver, orthodontic band pusher, orthodontic band setter, orthodontic bracket aligner, orthodontic pliers, orthodontic ligature tucking instrument, forceps, for articulation paper, forceps for dental dressing, dental matrix band, matrix retainer, dental retractor, dental retractor accessories, periodontic or endodontic irrigating syringe, and restorative or impression material syringe.

(b) *Classification.* Class I.

§ 872.4600 Intraoral ligature and wire lock.

(a) *Identification.* An intraoral ligature and wire lock is a metal device intended to constrict fractured bone segments in

the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.

(b) *Classification.* Class II.

§ 872.4630 Dental operating light.

(a) *Identification.* A dental operating light, including the surgical headlight, is an AC-powered device intended to illuminate oral structures and operating areas.

(b) *Classification.* Class II.

§ 872.4730 Dental injecting needle.

(a) *Identification.* A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs.

(b) *Classification.* Class I.

§ 872.4760 Bone plate.

(a) *Identification.* A bone plate is a metal device intended to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

(b) *Classification.* Class II.

§ 872.4840 Rotary scaler.

(a) *Identification.* A rotary scaler is an abrasive device intended to be attached to a powered handpiece to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.

(b) *Classification.* Class II.

§ 872.4850 Ultrasonic scaler.

(a) *Identification.* An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

(b) *Classification.* Class II.

§ 872.4880 Intraosseous fixation screw or wire.

(a) *Identification.* An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.

(b) *Classification.* Class II.

§ 872.4920 Dental electrosurgical unit and accessories.

(a) *Identification.* A dental electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is intended to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

(b) *Classification.* Class II.

§ 872.5410 Orthodontic appliance and accessories.

(a) *Identification.* An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.

(b) *Classification.* Class I.

§ 872.5470 Orthodontic plastic bracket.

(a) *Identification.* An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

(b) *Classification.* Class II.

§ 872.5500 Extraoral orthodontic headgear.

(a) *Identification.* An extraoral orthodontic headgear is a device intended for use with an orthodontic appliance to exert pressure on the teeth from outside the mouth. The headgear has a strap intended to wrap around the patient's neck or head and an inner bow portion intended to be fastened to the orthodontic appliance in the patient's mouth.

(b) *Classification.* Class II.

§ 872.5525 Preformed tooth positioner.

(a) *Identification.* A preformed tooth positioner is a plastic device that is an impression of a perfected bite intended to prevent a patient's teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.

(b) *Classification.* Class I.

§ 872.5550 Teething ring.

(a) *Identification.* A teething ring is a divice intended for use by infants for medical purposes to soothe gums during the teething process.

(b) *Classification.* (1) Class I if the teething ring does not contain a fluid, such as water.

(2) Class II if the teething ring contains a fluid, such as water.

Subpart G—Miscellaneous Devices

§ 872.6010 Abrasive device and accessories.

(a) *Identification.* An abrasive device and accessories is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The device is intended to remove excessive restorative materials, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece. The device includes the abrasive disk, guard for an abrasive disk, abrasive point, polishing agent strip, and polishing wheel.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6030 Oral cavity abrasive polishing agent.

(a) *Identification.* An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).

(b) *Classification.* Class I.

§ 872.6050 Saliva absorber.

(a) *Identification.* A saliva absorber is a device made of paper or cotton intended to absorb moisture from the oral cavity during dental procedures.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6070 Ultraviolet activator for polymerization.

(a) *Identification.* An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.

(b) *Classification.* Class II.

§ 872.6080 Airbrush.

(a) *Identification.* An airbrush is an AC-powered device intended for use in conjunction with articulation paper. The

device uses air-driven particles to roughen the surfaces of dential restorations. Uneven areas of the restorations are then identified by use of articulation paper. I11(b) *Classification.* Class III. I11(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.6100 Anesthetic warmer.

(a) *Identification.* An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.

(b) *Classification.* Class I.

§ 872.6140 Articulation paper.

(a) *Identification.* Articulation paper is a device composed of paper coated with an ink dye intended to be placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6200 Base plate shellac.

(a) *Identification.* Base plant shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.

(b) *Classification.* Class I. The device 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.

§ 872.6290 Prophylaxis cup.

(a) *Identification.* A prophylaxis cup is a device made of rubber intended to be held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6300 Rubber dam and accessories.

(a) *Identification.* A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth duing dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting the tooth through the hole in the center. The device includes the rubber dam, rubber dam clamp, rubber dam frame, and forceps for a rubber dam clamp.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6350 Ultraviolet detector.

(a) *Identification.* An ultraviolet detector is a device intended to provide a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.

(b) *Classification.* Class II.

§ 872.6390 Dental floss.

(a) *Identification.* Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

(b) *Classification.* Class I.

§ 872.6570 Impression tube.

(a) *Identification.* An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6650 Massaging pick or tip for oral hygiene.

(a) *Identification.* A massaging pick or tip for oral hygiene is a rigid, pointed device intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6660 Porcelain powder for clinical use.

(a) *Identification.* Porcelain powder for clinical use is a device consisting of a mixture of kaolin, felspar, quartz, or other substances intended for use in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in prosthetic dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.

(b) *Classification.* Class II.

§ 872.6670 Silicate protector.

(a) *Identification.* A silicate protector is a device made of silicone intended to be applied with an absorbent tipped applicator to the surface of a new restoration to exclude temporarily fluids from its surface.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6370 Endodontic dry heat sterilizer.

(a) *Identification.* An endodontic dry heat sterilizer is a device intended to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.6770 Cartridge syringe.

(a) *Identification.* A cartridge syringe is a device intended to inject anesthetic agents subcutaneously or intramuscularly. The device consists of a metal syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the syringe body and activating the carpule by partially

inserting the plunger on the syringe, the device is used to administer an injection to the patient.

(b) *Classification.* Class II.

§ 872.6855 Manual toothbrush.

(a) *Identification.* A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6870 Disposable flouride tray.

(a) *Identification.* A disposable fluoride tray is a device made of styrofoam intended to apply fluoride topically to the teeth. To use the tray, the patient bites down on the tray which has been filled with a fluoride solution.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6880 Preformed impression tray.

(a) *Identification.* A preformed impression tray is a metal or plastic device intended to hold impression material, such as alginate, to make an impression of a patient's teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient's teeth and gums.

(b *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

§ 872.6890 Intraoral dental wax.

(a) *Identification.* Intraoral dental wax is a device made of wax intended to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is intended to make a pattern of a patient's bite to make study models of the teeth.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it 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.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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