**CONTACT:** Vivian J. Arterbery, Executive Director (202) 382–0840.2

SUBMITTED:

**Jane D. McDuffie,**

*Staff Assistant.*

October 30, 1986.

[FR Doc. 86–25150 Filed 11–4–86; 10:03 am]

BILLING CODE 7527–01–M]

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5

**NATIONAL TRANSPORTATION SAFETY BOARD**

**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** 51 FR 40106, November 4, 1986.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:** 9 a.m., Thursday, November 13, 1986.

**CHANGE IN MEETING:** The following items have been added to the agenda and will be discussed in open session:

2. *Depositions:* Request for staff-conducted depositions regarding the collision of CSX Transportation Company freight train Extra 7593 with standing camp cars, Frenchton, West Virginia, September 3, 1986.

3. *Depositions:* Request for staff-conducted depositions regarding the bus/truck collision, I–295, Carney's Point, New Jersey, September 29, 1986.

**CONTACT PERSON FOR MORE INFORMATION:** H. Ray Smith (202) 382–6525.

**H. Ray Smith,**

*Federal Register Liaison Officer.*

November 4, 1986.

[FR Doc. 86–25230 Filed 11–4–86; 3:23 pm]

BILLING CODE 7533–01–M

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6

**POSTAL RATE COMMISSION**

**TIME AND DATE:** 10:00 a.m. on November 19, 1986.

**PLACE:** Conference Room, 1333 H Street, NW., Suite 300, Washington, DC.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** To consider motions to dismiss the Complaint of the Sacramento Bee et al., which is Docket No. C86–2.

**CONTACT PERSON FOR MORE INFORMATION:** Charles L. Clapp, Secretary, Postal Rate Commission, Room 300, 1333 H Street, NW., Washington, DC 20268–0001, Telephone (202) 789–6840.

**Charles L. Clapp,**

*Secretary.*

[FR Doc. 86–25248 Filed 11–4–86; 4:03 pm]

BILLING CODE 7715–01–M

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**SECURITIES AND EXCHANGE COMMISSION**

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of November 10, 1986:

A closed meeting will be held on Wednesday, November 12, 1986, at 2:30 p.m. An open meeting will be held on Thursday, November 13, 1986, at 10:00 a.m., in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Peters, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Wednesday, November 12, 1986, at 2:30 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

Settlement of administrative proceeding of an enforcement nature.

Opinion.

The subject matter of the open meeting scheduled for Thursday, November 13, 1986, at 10:00 a.m., will be:

1. Consideration of whether to solicit comment on proposed amendments to two Commission rules that would result in the designation as National Market System ("NMS") Securities of almost all listed securities, as well as the over-the-counter securities that currently are designated as NMS Securities, and on proposed companion rule changes filed by the National Association of Securities Dealers, Inc. For further information, please contact Andrew Feldman at (202) 272–2414.

2. Consideration of whether to adopt an amendment to Rule 31a–2 under the Investment Company Act of 1940 which would allow investment companies to store certain required records on magnetic tape, disk, or other computer storage medium. For further information, please contact John McGuire at (202) 272–7317.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Patrick Daugherty at (202) 272–3077.

**Shirley E. Hollis,**

*Assistant Secretary.*

October 31, 1986.

[FR Doc. 86–25197 Filed 11–4–86; 1:22 pm]

BILLING CODE 8010–01–M

federal register

Thursday
November 6, 1986

Part II

# Department of Labor

48 CFR Part 2901, Etc.
Acquisition Regulation Concerning Competition in Contracting; Interim Rule

## DEPARTMENT OF LABOR

### 48 CFR Parts 2901, 2902, 2903, 2905, 2906, 2909, 2913, 2914, 2915, 2916, 2917, 2919, 2933, 2943, and 2949

### Acquisition Regulation Concerning Competition in Contracting

**AGENCY:** Department of Labor.

**ACTION:** Interim rule; request for comments.

**SUMMARY:** This rule amends the Department of Labor Acquisition Regulation (DOLAR) to implement the Competition in Contracting Act of 1984 and Federal Acquisition Circular 84–5. The rule also makes editorial changes to the DOLAR.

**DATES:** The effective date of this rule is November 6, 1986, in order to effect implementation of the procedures under Federal Acquisition Circular 84–5. Written comments must be received on or before December 8, 1986 to be considered in the formulation of a final rule.

**ADDRESS:** Interested parties should submit written comments to Mr. Theodore Goldberg, Room S–1522, Office of Procurement and Grant Policy, Directorate of Administrative and Procurement Programs, Office of the Assistant Secretary for Administration and Management, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

**FOR FURTHER INFORMATION CONTACT:** Mr. Adam W. Hare. Telephone: (202) 523-9174.

**SUPPLEMENTARY INFORMATION:** The Department of Labor (DOL) has determined that this rule concerns agency procedures. These procedures are required for the DOL's implementation of the changes made to the Federal Acquisition Regulation resulting from the Competition in Contracting Act of 1984 (CICA), Pub. L. 98–369.

The purpose of this rule is to conform the DOLAR to revisions made to the FAR for implementing the Competition in Contracting Act of 1984. The FAR revisions were implemented under Federal Acquisition Circular 84–5. The rule also makes editorial changes to the DOLAR and implements revised procedures for filing protests with the General Accounting Office (GAO) and new procedures for filing automatic data processing protests with the General Services Administration Board of Contract Appeals (GSBCA) as required by CICA. Revisions were made to the FAR to implement the new bid protest procedures under Federal Acquisition Circular 84–6 dated January 15, 1985, and Federal Acquisition Circular 84–9 dated June 20, 1985. Prior notice and opportunity for public comment on this rule would be impracticable and contrary to the public interest in view of the need to implement the new protest procedures in as timely a manner as possible. In accordance with 5 U.S.C. 553(b)(3) (A) an (B), the Department has determined that prior notice and comment may be omitted. On the same basis, the Department has found good cause to make these regulations effective upon publication under 5 U.S.C. 553(d)(3).

#### Public Comment

Section 22 of the Office of Federal Procurement Policy Act, 41 U.S.C. 418(b), requires a 30 day notice and comment period for significant procurement regulations. Section 22(d) provides for the waiver of that period if urgent and compelling circumstances make compliance impracticable. In such cases, the regulation may be effective on a temporary basis where provision is made for a 30 day public comment period beginning on the date of notice of the temporary regulation. The Department has determined that the need to implement the new protest procedures in a timely manner constitutes urgent and compelling circumstances permitting the issuance of this regulation on a temporary basis with provision for a 30 day comment period.

#### Regulatory Impact

This rule does not have the financial or other impact to make it a major rule, and, therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291, 3 CFR, 1981 Comp., p. 127, 5 U.S.C. 601 note.

The rule appears not to 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 imposes no new requirements which would require such entities to change their business practices, incur additional costs or otherwise affect their competitive position.

The Department of Labor has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification pursuant to 5 U.S.C. 605(b), that the rule will not have a significant economic impact on a substantial number of small entities. The rule revises existing Department-wide acquisition regulations and contains no new requirements on small entities beyond those prescribed by the Competition in Contracting Act of 1984.

#### Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

#### List of Subjects in 48 CFR Parts 2901, 2902, 2903, 2905, 2906, 2909, 2913, 2914, 2915, 2916, 2917, 2919, 2933, 2943 and 2949

Government procurement.

For the reasons set out in the preamble, Chapter 29 of Title 48 of the Code of Federal Regulations is amended as set forth below.

Signed at Washington, DC, this 29th day of October, 1986.

**Thomas K. Delaney,**

*Procurement Executive.*

**Thomas C. Komarek,**

*Assistant Secretary for Administration and Management.*

## PART 2901—DEPARTMENT OF LABOR ACQUISITION REGULATION SYSTEM

1. The Authority citation for 48 CFR Part 2901 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

2. The heading for Part 2901 is revised to read as set forth above.

3. Section 2901.603–1 is amended as follows:

a. In paragraph (a)(3), the words, "input for" are removed from the second sentence;

b. In paragraph (d)(8)(i), the word "copiers" in the last sentence is revised to read "copier"; and

c. Paragraphs (d)(4)(iii), (d)(9), (f)(2), (g)(2), and (g)(3) are revised to read as follows:

**2901.603–1 General.**

* * * * *

(d) * * *

(4) * * *

(iii) The purchase, lease, or renewal of lease(s) of ADP equipment, software and services costing $100,000 or less without prior approval of the Directorate of Information Resources Management (DIRM), OASAM. Requirements shall not be fragmented in order to circumvent this $100,000 threshold. ADP equipment, software or services costing more than $100,000 require prior approval of DIRM. Prior approval of DIRM for ADP equipment, software, or services costing less than $100,000 is also required when costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201–23.104.

* * * * *

(9) The Director, National Capital Service Center, OASAM, or an officer acting in that capacity, is delegated authority and responsibility for acquisition of all property and services on behalf of DOL activities except for those contracting and grant responsibilities designated above. This includes (except for the Mine Safety and Health Administration (MSHA)) acquisition authority for the purchase, lease, and renewal of lease(s) of all ADP equipment, software and all ADP services where Agencies have obtained prior approval from the Directorate of Information Resources Management (DIRM), OASAM, as appropriate.

* * * * *

(f) * * *

(2) The Director, Directorate of Information Resources Management (DIRM), OASAM, or an officer acting in that capacity, is responsible for:

(i) Reviewing and providing prior approval for the purchase, lease or renewal of lease(s) of ADP equipment, software and services costing $100,000 or more (the purchase price is to be used to determine inclusion in this paragraph regardless of whether the item is to be purchased or leased) and for all ADP services. Requirements shall not be fragmented in order to circumvent this $100,000 threshold. Reviews involving lower amounts will be made when costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201-23.104.

(ii) Providing oversight, including periodic system reviews, to promote efficient and effective management of information technology resources.

(iii) Reviewing ADP procurement requests for compliance with procurement policies, standards, and regulations.

(iv) Representing DOL and agencies in DOL in liaison with GSA and OMB on ADP matters.

(v) Developing and publishing policies and guidelines for managing information technology resources.

* * * * *

(g) * * *

(2) *Automated data processing (ADP).* The following requirements and limitations exist for the purchase or lease of ADP equipment, software and services:

(i) Authority to issue purchase orders and contracts is limited only to those officials in paragraph (b) with procurement responsibility explicitly including this authority.

(ii) Acquisition of ADP equipment, software and services costing $100,000 or more requires prior approval of DIRM, OASAM.

(iii) Acquisition of ADP equipment, software and services costing less than $100,000 do not require prior approval of DIRM, OASAM, unless costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201-23.104. However, agencies are responsible for complying with FIRMR documentation requirements.

(3) *Records equipment.* The purchase of records equipment; defined as file cabinets, shelf files, visible files, mechanized files, files guides, folders, jackets, wallets, and similar items used in the creation and maintenance of records and in mail handling requires special authority. Federal Property Management Regulation 101-11.306 as implemented by the Department of Labor Manual Series (DLMS-1) requires that: Form DL 1-194 be completed by the Agency Records Officer and forwarded to the Departmental Records Officer, DIRM, OASAM, for approval prior to acquisition. Regional Administrators—OASAM are delegated this approval authority for their respective regions. In keeping with GSA Bulletins FPMR B-120 and B-122 which discourage the use of legal-size files, no new legal size records equpment is to be purchased.

* * * * *

4. A new section 2901.603-74 is added to read as follows:

**2901.603-74 Legal review and assistance.**

Proposed acquisitions may be subject to legal review by the Office of the Solicitor of Labor. Internal DOL procedures are contained in the Department of Labor Manual Series (DLMS-2, Chapter 900, Section 910). Copies of the DLMS Chapter may be obtained upon written request from the Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

## PART 2902—DEFINITION OF WORDS AND TERMS

5. The Authority citation for Part 2902 is revised to read as follows and the separate Authority citations following the sections in Part 2902 are removed:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 486(c).

6. Section 2902.101 is amended by adding definitions for "Head of procuring activity" and for "Procuring activity", and by revising the definitions for "Automated Data Processing (ADP)" and "Procurement Executive", as follows:

**2902.101 Definitions.**

* * * * *

"Automated Data Processing (ADP)," as used throughout this document, is defined as Information Technology. Information Technology means the merging of three technologies: automated data processing, office automation and telecommunications. Information technology resources include automated data processing (ADP) equipment, software, maintenance, related supplies, services, general purpose facilities for office automation, and data and integrated voice/data telecommunications services, facilities, and equipment.

* * * * *

"Head of procuring activity" means the Assistant Secretary for Administration and Management; the Assistant Secretary for Employment and Training; the Assistant Secretary for Mine Safety and Health, and the Director, National Capital Service Center.

* * * * *

"Procurement Executive" means the Director, Directorate of Procurement and Grant Management, and is synonymous with the term "Senior Procurement Executive" defined at FAR Subpart 2.1. Responsibilities of the Procurement Executive include appointing the DOL advocate for competition.

"Procuring activity" means the Office of the Assistant Secretary for Administration and Management; the Employment and Training Administration; the Mine Safety and Health Administration; and the National Capital Service Center.

## PART 2903—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

7. The Authority citation for Part 2903 continues to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 486(c).

**2903.204 [Amended]**

8. Section 2903.204(a) is amended by revising the word "Afer" in the first sentence to read "After".

## PART 2905—PUBLICIZING CONTRACT ACTIONS

9. The Authority citation for Part 2905 continues to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 486(C).

10. A new Subpart 2905.2 is added to read as follows:

### Subpart 2905.2—Synopsis of Proposed Contract Actions

**2905.202 Exceptions.**

The Procurement Executive is authorized to make the determination prescribed in FAR 5.202(b). A written determination documenting the reasons why advance notice is not appropriate or reasonable shall be submitted by the HCA to the Director, Directorate of Procurement and Grant Management, for appropriate action including communication with the officials listed in FAR 5.202(b).

11. A new Part 2906 is added to 48 CFR Chapter 29, to read as follows:

## PART 2906—COMPETITION REQUIREMENTS



Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

### Subpart 2906.2—Full and Open Competition After Exclusion of Sources

**2906.202 Establishing or maintaining alternative sources.**

The Procurement Executive is authorized to make the determination prescribed in FAR 6.202(b). A written determination shall be submitted by the HCA to the Director, Directorate of Procurement and Grant Management.

### Subpart 2906.3—Other Than Full and Open Competition

**2906.303 Justifications.**

**2906.303–1 Requirements.**

(a) As prescribed in the Department of Labor Manual Series (DLMS) 2, Chapter 830, any proposed noncompetitive aquisitions in excess of the small purchases limitation must be fully justified, submitted to the DOL Procurement Review Board and approved by the Assistant Secretary for Administration and Management and, in the case of research contracts, by the Assistant Secretary for Policy.

(b) The contracting officer is responsible for assuring that proposed acquisitions below the dollar level specified in paragraph (a) of this section are in compliance with FAR and DOLAR requirements regarding competition.

### Subpart 2906.5—Competition Advocates

**2906.501 Requirement.**

(a) The Competition Advocate for the Department of Labor is the Director, Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, OASAM.

(b) The head of the agency has delegated the authority to the Procurement Executive to appoint the Agency and Procuring Activity Competition Advocates. The Procurement Executive has delegated authority to the Head of the Procuring Activity to appoint Procuring Activity Competition Advocates.

## PART 2909—CONTRACTOR QUALIFICATIONS

12. The Authority citation for Part 2909 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

13. Section 2909.105–1 is amended by revising paragraph (b) to read as follows:

**2909.105–1 Procedures.**

* * * * *

(b) Contracting officers may obtain credit reports prior to the issuance of any loan, loan guarantee, contract or grant through the credit bureau service. The National Capital Service Center will award a contract for the credit bureau service for use by all DOL contracting activities until such services become available through an established GSA Federal Supply Schedule.

## PART 2913—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

14. The Authority citation for Part 2913 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

**2913.403 [Amended]**

15. Section 2913.403 is amended by revising the word "System" in the first sentence to read "Series".

**2913.503–70 [Amended]**

16. Section 2913.503–70 is amended by revising the word "orignal" in the first sentence of the second paragraph to read "original".

## PART 2914—SEALED BIDDING

17. The Authority citation for Part 2914 continues to read:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

18. The part heading of Part 2914 is revised to read as set forth above.

19. Sections 2914.404 and 2914.404–1 are added to read as follows:

**2914.404 Rejection of bids.**

**2914.404–1 Cancellation of invitations after opening.**

The head of the contracting activity (HCA) is authorized to make the written determination required by FAR 14.404–1(c).

20. Section 2914.407–8 is revised to read as follows:

**2914.407–8 Protests against award.**

See DOLAR subpart 2933.1, "Protests".

## PART 2915—CONTRACTING BY NEGOTIATION

21. The Authority citation for Part 2915 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

### Subparts 2915.1, 2915.2, and 2915.3 [Removed]

22. Part 2915 is amended by removing Subparts 2915.1, 2915.2 and 2915.3.

23. Section 2915.608 is added to read as follows:

**2915.608 Proposal evaluation.**

The head of contracting activity (HCA) is authorized to make the determination required by FAR 15.608(b).

## PART 2916—TYPES OF CONTRACTS

24. The authority citation for Part 2916 continues to read; as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

25. A new Subpart 2916.3 is added to read as follows:

### Subpart 2916.3—Cost-Reimbursement Contracts

**§ 2916.306 Cost-plus-fixed-fee contracts.**

The Contracting Officer is authorized to approve the determination establishing the basis for application of the statutory price or fee limitation prescribed in FAR 16.306(c)(2).

## PART 2917—SPECIAL CONTRACTING METHODS

26. The Authority citation for Part 2917 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c)

27. Section 2917.502 is revised to read as follows:

**2917.502 General.**

The head of the contracting activity is authorized to make the determination prescribed in FAR 17.502 in accordance

with the requirements contained in FAR 17.503.

## PART 2919—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

28. The Authority citation for Part 2919 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

### 2919.202-1 [Amended]

29. Section 2919.202–1 is amended as follows:

a. In paragraph (a), the dollar amount "$2,500" is revised to read "$10,000".

b. In paragraph (b), the word "and" is added at the end thereof; and

c. In paragraph (c), the words "synopsis message; and" are revised to read "synopsis message.".

## PART 2933—PROTESTS, DISPUTES, AND APPEALS

30. The Authority citation for Part 2933 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

31. The part heading for Part 2933 is revised to read as set forth above.

32. Part 2933 is amended by adding a new subpart 2933.2, to read as follows:

### Subpart 2933.2—Disputes and Appeals

### 2933.003, 2933.003-70, 2933.009, 2933.011 and 2933.012 [Redesignated]

33. Sections 2933.003, 2933.003–70, 2933.009, 2933.011 and 2933.012 are redesignated in the new Subpart 2933.2, with redesignated section numbers as set forth in the following table:

| Old Section: | *New Section (In Subpart 2933.2)* |
|---|---|
| 2933.003 | 2933.203 |
| 2933.003–70 | 2933.203–70 |
| 2933.009 | 2933.209 |
| 2933.011 | 2933.211 |
| 2933.012 | 2933.212 |

### 2933.203 [Amended]

34. In paragraph (a) of newly redesignated section 2933.203, the citation "33.003(b)" is revised to read "33.203(b)".

### 2933.211 [Amended]

35. In the first sentence of newly redesignated section 2933.211, the phrase "The written decision required by FAR 33.011 (a)(4) shall include, in the paragraph listed under FAR 33.011(a)(4)(v)," is revised to read "The written decision required by FAR 33.211(a)(4) shall include, in the paragraph listed under FAR 33.211(a)(4)(v),".

36. Part 2933 is amended by adding a new Subpart 2933.1 consisting of sections 2933.102 through 2933.105, to read as follows:

### Subpart 2933.1—Protests

### 2933.102 General.

The Director, Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, shall be responsible for coordinating bid protests filed with the General Accounting Office (GAO). All communications relative to protests filed with GAO or GSBCA shall be coordinated with the Director, Office of Procurement and Grant Policy. Bid protests concerning automatic data processing (ADP) acquisitions filed with the General Services Administration Board of Contract Appeals (GSBCA) shall be coordinated by the contracting officer.

### 2933.103 Protests to the DOL Agency.

When protests are filed with a DOL Agency and received before award, the contracting office shall obtain the advice of the Director, Office of Procurement and Grant Policy, before making the determination under FAR 33.103(a).

### 2933.104 Protests to the GAO.

(a) *Notice of protest.* Upon being advised telephonically by GAO or the receipt of a protest before or after award, the Office of Procurement and Grant Policy shall inform the appropriate contracting officer and request preparation of the protest report required by FAR 33.104(a)(2). For GAO protests concerning ADP acquisitions, the Office of Procurement and Grant Policy shall also inform the Director, Directorate of Information Resources Management, who, in turn, shall notify the appropriate DOL Agency Information Resources Management (IRM) contact. As required by FAR 33.104(a)(3) and 4 CFR 21.3, the contracting officer shall promptly notify all interested parties, including offerors (or the contractor, if the protest is after award) involved in or affected by the protest, that a protest has been filed with GAO and the basis for the protest. A written record of such notification shall be placed in the contract file. After receiving a copy of the protest from GAO and its request for an administrative report, the Office of Procurement and Grant Policy will promptly furnish the same to the contracting officer. The contracting officer shall promptly transmit by letter a copy of the protest to all interested parties previously notified and include a statement requiring furnishing of views and information directly to GAO. Copies of cover letters shall be sent to the Director, Office of Procurement and Grant Policy. Cover letters shall set forth a specified period of time for submission of comments (see FAR 33.104(a)(3)) and include instructions that any comments submitted to GAO should also be submitted simulaneously to the contracting officer and the Director, Office of Procurement and Grant Policy. Materials submitted by the protester may be withheld from interested parties in accordance with 4 CFR 21.3(b).

(b) *Submission of report.* (1) All personnel shall handle protests on a priority basis. Within 25 work days after receipt by the Office of Procurement and Grant Policy of GAO's telephonic notice of the protest, or within 10 work days after receipt from GAO of a determination to use the express option, a complete report shall be submitted to GAO (see FAR 33.104(a)(2)). If the specific circumstances of the protest require a longer period, the head of the contracting activity shall immediately notify the Office of Procurement and Grant policy which shall request, in writing, an extension of the time period in accordance with 4 CFR 21.3(d).

(2) In addition to the requirements of FAR 33.104(a)(2), the report responsive to the protest shall be appropriately titled and dated; shall cite the GAO file number; and shall be signed by the contracting officer or the contracting officer's representative. Reports shall be prepared with the assistance of the Office of the Solicitor of Labor. If appropriate, the report shall contain a statement regarding any urgency for the acquisition and the extent to which a delay in award may result in significant performance difficulties or additional expense to the Government. If award is not urgent, a statement shall be included giving an estimate of the length of time an award may be delayed without significant expense or difficulty in performance. The head of the contracting activity shall submit an original and one copy of the contracting officer's report to the Director, Office of Procurement and Grant Policy, with a forwarding letter to GAO signed by the Assistant Secretary for Administration and Management. When the letter and report are dated and transmitted to GAO, the Director, Office of Procurement and Grant Policy, will inform the contracting officer. The contracting officer will then distribute copies of the report to all interested parties.

(c) *Notice to GAO.* The Assistant Secretary for Administration and

Management shall submit the report required by FAR 33.104(f). The report shall be submitted to the Comptroller General through the Director, Office of Procurement and Grant Policy, and the Director, Directorate of Procurement and Grant Managemnent. For decisions concerning ADP acquisitions, the report shall also be submitted through the Director, Directorate of Information Resources Management.

**2933.105 Protests to General Services Administration Board of Contract Appeals.**

(a) *Notice of protest.* Immediately upon receipt of a copy of a protest to the General Services Administration Board of Contract Appeals (GSBCA), the contracting officer shall inform the Office of Procurement and Grant Policy, the Directorate of Information Resources Management, and the Office of the Solicitor of Labor. The contracting officer shall, within 1 work day after receipt of a copy of the protest, provide oral or written notice to all parties required to be notified by FAR 33.105(a)(2) and shall provide the GSBCA with a written list of all such parties to whom notice was provided within 5 work days after receipt of a copy of the protest. A copy of all notifications to interested parties and related correspondence with GSBCA shall be maintained in the contract file and a copy of the list of interested parties notified shall be provided to the Office of Procurement and Grant Policy simultaneously with submission to the GSBCA.

(b) *Submission of protest file.* An original and one copy of a protest file (see FAR 33.105(b)) plus one copy for each interested party which has a notice of intervention or a motion to intervene in accordance with the requirements of Rule 5(a)(3) of GSBCA Rules of Procedure (48 CFR 6101.5(a)(3)) shall be prepared by the contracting officer. The protest file shall be organized to comply with the requirements of Rule 4(b) of the GSBCA Rules of Procedure (48 CFR 6101.4(b)). The contracting officer shall submit the file to the GSBCA within 10 work days after filing of the protest and shall also send copies to the Director, Office of Procurement and Grant Policy, and to each interested party.

(c) *Hearings.* The Solicitor of Labor, or the Solicitor's representative, is responsible for representing the contracting officer at all stages of proceedings on suspension of the agency's delegation of procurement authority (see FAR 33.105(d)), at all stages of proceedings on the merits of the protest (see FAR 33.105(e)), and with respect to any other proceedings which may be heard by the GSBCA. The head of the contracting activity shall be responsible for executing the determination required by FAR 33.105(d)(1). The Office of the Solicitor shall notify the contracting officer and the Directorate of Information Resources Management of the results of such proceedings, including any hearing.

## PART 2943—CONTRACT MODIFICATIONS

37. The Authority citation for Part 2943 is revised to read as follows, and the separate Authority citations for sections in the part are removed:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 486(c).

38. Part 2943 is amended by adding a new subpart 2943.3 to read as follows:

### Subpart 2943.3—Forms

**2943.301 Use of forms.**

FAR 43.301(a)(1)(vi) requires the use of Standard Form 30 (SF–30) to effect any obligation or deobligation of contract funds after award. The SF–30 also shall be used to deobligate funds when effecting contract closeout for a cost reimbursement contract when obligated funds exceed the final contract costs. In such an instance, the SF–30 may be issued as an administrative modification on a unilateral basis if the contractor's financial release has been separately obtained.

## PART 2949—TERMINATION OF CONTRACTS

39. The Authority citation for Part 2949 continues to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 486(c).

### Subpart 2949.1—General Principles

40. Part 2949.1 is amended by revising the subpart heading to read as set forth above

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Part III

# Department of Health and Human Services

## Food and Drug Administration

**21 CFR Parts 868, 874, 878, and 886**
**Medical Devices; Ear, Nose, and Throat Devices; Final Rule, Proposed Rule and Withdrawal of Proposed Rules**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 868 and 874**

**[Docket No. 78N-1549]**

## Ear, Nose, and Throat Devices; General Provisions and Classifications of 47 Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying 47 devices: 45 ear, nose, and throat devices and 2 anesthesiology devices. The preamble to this rule responds to comments received on the proposed regulations classifying these devices. This action is being taken under the Medical Device Amendments of 1976.

**EFFECTIVE DATE:** December 8, 1986.

**FOR FURTHER INFORMATION CONTACT:** David A. Segerson, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8185.

**SUPPLEMENTARY INFORMATION:**

Table of Contents



### A. Background

In the **Federal Register** of January 22, 1982 (47 FR 3280-3325), FDA published a proposed rule containing general provisions applicable to the classification of ear, nose, and throat devices and individual proposed regulations classifying 67 ear, nose, and throat devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval).

In the final rule, FDA is classifying 47 devices, with 14 devices in class I, 26 devices in class II, 5 devices in class III, 1 device in either class I or class II (depending upon its construction), and 1 device in either class II or class III (depending upon its intended use).

For several reasons, there is a difference between the number of devices covered by the proposal (67) and the number of devices covered by the final rule (47). First, FDA has grouped 23 devices that were the subjects of proposed regulations into 9 generic types of devices, resulting in 14 fewer devices. Second, FDA is postponing classification of six devices pending review of additional data. Third, FDA is announcing its decision on a reclassification petition for the microsurgical argon laser for use in otology and is codifying the reclassification of this device into class II for certain intended uses; however, the device remains in class III for other intended uses. Fourth although FDA proposed that the transdermal stimulator (§ 874.5850, Docket No. 78N-1636) be classified into class III (47 FR 3280) as part of the ear, nose, and throat device classification proceeding, the agency later determined that the device is an investigational device not in commercial distribution before May 28, 1976, the enactment date of the amendments. Because the device was not in commercial distribution, the transdermal stimulator is classified into class III by statute as provided in section 513(f) of the act (21 U.S.C. 360c), without the need for agency publication of a classification regulation for the device.

Two proposed ear, nose, and throat devices, the tracheostomy tube and tube cuff (class II) and the tracheal tube cleaning brush (class I), are being codified with anesthesiology devices in 21 CFR Part 868. Therefore, in this final rule, FDA is classifying 45 ear, nose, and throat devices and 2 anesthesiology devices.

Elsewhere in the issue of the **Federal Register**, FDA is publishing a notice withdrawing the proposed regulations that are unnecessary due to the decisions described above.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule proposing to exempt from the requirement of premarket notification, with limitations, four class I ear, nose, and throat devices.

Classification of medical devices in commercial distribution is required by section 513 (21 U.S.C. 360c) of 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 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 that was not considered a new drug before the amendments and 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 June 28, 1989, or within 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(1) and 513(f) of the act (21 U.S.C. 360j(l) and 360c(f)).

The preamble to the proposed rule described the development of the general provisions and the proposed regulations classifying ear, nose, and throat devices and the activities of the FDA advisory committee that makes recommendations to FDA concerning the classification of ear, nose, and throat devices. FDA provided a period of 60 days for interested persons to submit written comments on the proposals. The deadline was later extended to July 1, 1982. The comments received and FDA's responses to the comments are discussed in section "K. Summaries of Comments and FDA's Responses to Comments" of this preamble.

In April 1985, H.R. 2177 (99th Cong. 1st Sess.) was introduced in the U.S. House of Representatives. The bill is a legislative proposal of the Department of Health and Human Services. Among other things, the bill would (1) and amend the act to eliminate the statutory category of class II, (2) make the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamline the procedure for establishing standards set out in section 514 of the act. If this bill becomes law, there will be only two

categories of devices, class I (general controls) and class II (premarket approval, formerly class III). Class II devices would be redesignated as class I devices. Because this legislation includes transitional provisions that translate classifications under the current law to classifications under the proposed law, FDA is continuing its issuance of classification rules under the current law and has established a policy, described below, to set priorities for the establishment of performance standards for class II devices.

### B. FDA's Priorities for Establishing Performance Standards

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

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

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

### C. Changes in the Name of the Ear, Nose, and Throat Device Advisory Committee

FDA has periodically restructured its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Ear, Nose, and Throat Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to ear, nose, and throat devices as did its predecessors, the Ear, Nose, and Throat Device Classification Panel (1976–1978) and the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel (1978–1984).

### D. Grouping of Similar Devices

In response to comments and to simplify and clarify the regulations, in the final rule FDA has grouped 23 proposed ear, nose, and throat devices into 9 generic types of devices. The term "generic type of device" is defined in 21 CFR 860.3(i) to mean a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness. Consequently, similar regulatory controls are appropriate to provide reasonable assurance of the safety and effectiveness of these devices. The devices being grouped are identified below under the heading in the preamble entitled "J. List of Ear, Nose, and Throat Devices." Each generic type of ear, nose, and throat device being classified is identified with both the docket number 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 under the heading "J. List of Ear, Nose, and Throat Devices" that is not identified with a section number is being grouped into the generic type of device with a section number that is listed directly before it. Thus, for example, *Air caloric stimulator* and *Water caloric stimulator* are being grouped into the generic type of device *Air or water caloric stimulator* (§ 874.1800).

### E. Devices Not Being Classified at This Time

FDA is postponing classification of the following six generic types of ear, nose, and throat devices in order to review additional data on electrical safety. Because similar ear, nose, and throat devices are being grouped as described above, the six generic types of devices encompass devices that were the subjects of eight proposed regulations. The following is a list of the six generic types of devices that are not being classified in the final rule. FDA is considering classifying these six devices in class I.

| Docket No. | Device |
|---|---|
| 78N-1552 | Short increment sensitivity index (SISI) adapter. |
| 78N-1565 | Air or water caloric stimulator. |
| 78N-1622 | Laryngostroboscope. |
| 78N-1624 | Otoscope. |
| 78N-1630 | Ear, nose, and throat examination and treatment unit. |
| 78N-1631 | Powered nasal irrigator. |

### F. Changes in Classifications in Final Regulations

Based upon consideration of the comments received and on additional consideration of all information before the agency, FDA has placed several devices that are listed below in different classes from those proposed. FDA's reasons for adopting classifications for these devices that differ from the proposal are provided in this preamble under the heading "K. Summaries of Comments and FDA's Responses to Comments."

| Secs. | Device | Proposed class | Final class |
|---|---|---|---|
| 874.1060 | Acoustic chamber for audiometric testing. | II | I |
| 874.1100 | Earphone cushion for audiometic testing. | II | I |
| 874.3300 | Hearing aid | II | I, II |
| 874.3450 | Partial ossicular replacement prothesis. | II, III | II |
| 874.3495 | Total ossicular replacement prosthesis. | II, III | II |
| 874.3630 | Ear, nose, and throat porous polyethylene synthetic polymer material. | III | II |
| 874.3880 | Tympanostomy tube | II, III | II |
| 874.4140 | Ear, nose, and throat bur. | II | I |
| 874.4420 | Ear, nose, and throat manual surgical instrument. | II | I |
| 874.5840 | Antistammering device. | II | I |

FDA believes that it is unnecessary 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, or upon reconsideration, the agency may determine that its proposed classification is incorrect. Persons interested in the classification process should 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 regulations for ear, nose, and throat devices (see 47 FR 3280; January 22, 1982). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860.

### G. 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. Additionally, the agency is adding new § 874.3 in Subpart A to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a 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.

### H. Reclassification of the Microsurgical Argon Laser

Postamendments devices that are not substantially equivalent to devices in commercial distribution before May 28, 1976, are classified by statute into class III under section 513(f)(1) of the act (21 U.S.C 360c(f)(1)). In response to a petition received by FDA under section 513(f)(2) of the act and Part 860 of the regulations, FDA may reclassify a new device into class I or class II.

On October 15, 1980, FDA received a petition (Docket No. 81P-0115) under section 513(f) of the act requesting the agency to reclassify the petitioner's Model 770 argon laser with microsurgical attachments for use in otolarynogological surgery from class III to class II. On December 4, 1980, FDA received a petition (Docket No. 80P-0501) under section 513(e) of the act (21 U.S.C. 360(e)) requesting the agency to reclassify the petitioner's Model 9005 argon laser with microsurgical attachments for use in otology from class III to class II. In the **Federal Register** of May 11, 1982 (47 FR 20188), FDA published the recommendations of the Ear, Nose, and Throat Devices Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel that both of these devices be reclassified from class III to class II and treated as one generic type of device. The agency provided a period of 30 days (extended to 60 days by notice of July 2, 1982 (47 FR 29004)) for interested persons to submit written comments on the recommendations. No written comments were received. FDA agreed with the section's recommendations that the device be reclassified. Further, the Section recommended, and FDA agrees, that the labeling for the device include a comprehensive description of the techniques, risks, and hazards which accompany use of the device, as well as a discussion on how the attendant risks and hazards can be avoided. In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA partially approved and partially denied the petitions and, by orders in the form of letters dated November 19, 1982, and sent to each petitioner, reclassified the microsurgical argon laser for use in otology from class III to class II. However, the microsurgical argon laser for other uses, including use in laryngology and general use in otolaryngology, remains in class III and may not be commercially distributed without an approved application for premarket approval.

FDA is codifying the reclassification into class II of the microsurgical argon laser for use in otology at § 874.4490(a). FDA's orders reclassifying the device for certain uses into class II and the regulation apply to any microsurgical argon laser for use of otology that 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 Part 807.

### I. Classification Regulations Published to Date

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

| Panel name | Publication date in FEDERAL REGISTER |
|---|---|
| Circulatory System Devices Panel | Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations). |
| Clinical Chemistry and Clinical Toxicology Devices Panel. | Feb. 2, 1982, 47 FR 4802-4929 (proposals). |
| Hematology and Pathology Devices Panel. | Sept. 11, 1979, 44 FR 53063 (proposals); Sept. 12, 1980, 45 FR 60576-6051 (final regulations). |
| General Hospital and Personal Use Devices Panel. | Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980 45 FR 69678-69737 (final regulations). |
| Gastroenterolgy-Urology Devices Panel. | Jan. 23, 1981, 46 FR 7562-7641 (proposals); Nov. 23, 1983, 48 FR 53012-53029 final regulations). |
| Immunology Devices Panel | Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50614-50640 (final regulations). |
| Microbiology Devices Panel | Do. |
| Obstetrics-Gynecology Devices Panel. | Apr. 3, 1979, 44 FR 19894-19971 (proposals); Feb. 26, 1980, 45 FR 12682-12720 (final regulations). |
| Radiologic Devices Panel | Jan. 29, 1982, 47 FR 4406-4451 (proposals). |
| Ophthalmic Devices Panel | Jan. 26, 1982, 47 FR 3694-3749 (proposals). |
| Ear, Nose, and Throat Devices Panel. | Jan. 22, 1982, 47 FR 3280-3325 (proposals); (Nov. 6, 1986 (final regulations)l |
| Dental Devices Panel | Dec. 30, 1980, 45 FR 85962-86168 (proposals). |
| Anesthesiology and Respiratory Therapy Devices Panel. | Nov. 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations). |
| Neurological Devices Panel | Nov. 23, 1978, 43 FR 54640-55732 (proposals); Sept. 4, 1979, 44 FR 51726-51778, (final regulations). |
| Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices). | Aug. 28, 1979, 44 FR 50458-50537 (proposals); Nov. 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. | Jan. 19, 1982, 47 FR 2810-2853 (proposals). |

### J. List of Ear, Nose, and Throat Devices

The list below shows for each ear, nose, and throat 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 of the corresponding proposed classification regulation (where applicable), the final classification of the device, and an identification (yes or no) of whether public comments were received on the proposed regulation. If no comments were received, generally FDA is adopting the proposed regulation without a change in classification. The list includes the six generic types of ear, nose, and throat devices for which final classification is being postponed. For each of these six devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "1," and no final classification is provided.

| Section | Device | Docket No. | Class | Comments |
|---|---|---|---|---|
| | **SUBPART B—DIAGNOSTIC DEVICES** | | | |
| 874.1050 | Audiometer | 78N-1550 | II | Yes. |
| 874.1060 | Acoustic chamber for audiometric testing | 78N-1551 | I | Yes. |
| (874.1070) | Short increment sensitivity index (SISI) adapter [1] | 78N-1552 | | Yes. |
| 874.1080 | Audiometer calibration set | 78N-1553 | II | Yes. |
| 874.1090 | Auditory impedance tester | 78N-1554 | II | Yes. |
| 874.1100 | Earphone cushion for audiometric testing | 78N-1555 | I | Yes. |
| 874.1120 | Electronic noise generator for audiometric testing | 78N-1556 | II | Yes. |
| 874.1325 | Electroglottograph | 78N-1558 | II | Yes. |
| 874.1500 | Gustometer | 78N-1561 | I | No. |
| (874.1800) | Air or water caloric stimulator [1] | 78N-1565 | | |
| | Air caloric stimulator | 78N-1565 | | Yes. |
| | Water caloric stimulator | 78N-1566 | | Yes. |
| 874.1820 | Surgical nerve stimulator/locator | 78N-1567 | II | Yes. |
| 874.1925 | Toynbee diagnostic tube | 78N-1568 | I | No. |
| | **SUBPART D—PROSTHETIC DEVICES** | | | |
| 874.3300 | Hearing aid | 78N-1569 | I, II | Yes. |
| 874.3310 | Hearing aid calibrator and analysis system | 78N-1570 | II | Yes. |
| 874.3320 | Group hearing aid or group auditory trainer | 78N-1571 | II | Yes. |
| 874.3330 | Master hearing aid | 78N-1572 | II | Yes. |
| 874.3375 | Battery-powered artificial larynx | 78N-1573 | I | No. |
| 874.3400 | Tinnitus masker | 78N-1574 | III | No. |
| 874.3430 | Middle ear mold | 78N-1576 | II | Yes. |
| 874.3450 | Partial ossicular replacement prosthesis | 78N-1577 | II | |
| | Partial ossicular replacement prosthesis | 78N-1577 | | Yes. |
| | Porous polyethylene partial ossicular replacement prosthesis | 78N-1637 | | Yes. |
| 874.3495 | Total ossicular replacement prosthesis | 78N-1578 | II | |
| | Total ossicular replacement prosthesis | 78N-1578 | | Yes. |
| | Porous polyethylene total ossicular replacement prosthesis | 78N-1639 | | Yes. |
| 874.3540 | Prosthesis modification instrument for ossicular replacement surgery | 78N-1579 | I | No. |
| 874.3620 | Ear, nose, and throat synthetic polymer material | 78N-1583 | II | |
| | Ear, nose, and throat polyamide mesh or foil synthetic polymer material | 78N-1583 | | Yes. |
| | Ear, nose, and throat porous polyethylene synthetic polymer material | 78N-1584 | | Yes. |
| 874.3695 | Mandibular implant facial prosthesis | 78N-1588 | II | Yes. |
| 874.3730 | Laryngeal prosthesis (Taub design) | 78N-1589 | II | Yes. |
| 874.3760 | Sacculotomy tack (Cody tack) | 78N-1591 | II | Yes. |
| 874.3820 | Endolymphatic shunt | 78N-1593 | II | Yes. |
| 874.3850 | Endolymphatic shunt tube with valve | 78N-1594 | III | Yes. |
| 874.3880 | Tympanostomy tube | 78N-1595 | II | |
| | Tympanostomy tube | 78N-1595 | | Yes. |
| | Porous polyethylene tympanostomy tube | 78N-1641 | | Yes. |
| 874.3930 | Tympanostomy tube with semipermeable membrane | 78N-1596 | III | Yes. |
| | **SUBPART E—SURGICAL DEVICES** | | | |
| 874.4100 | Epistaxis balloon | 78N-1599 | I | No. |
| 874.4140 | Ear, nose, and throat bur | 78N-1601 | I | Yes. |
| 874.4175 | Nasopharyngeal catheter | 78N-1602 | I | No. |
| 874.4250 | Ear, nose, and throat electric or pneumatic surgical drill | 78N-1604 | II | Yes. |
| 874.4350 | Ear, nose, and throat fiberoptic light source and carrier | 78N-1606 | II | Yes. |
| 874.4420 | Ear, nose, and throat manual surgical instrument | 78N-1609 | I | |
| | Bronchial, tracheal, or esophageal surgical instrument | 78N-1607 | | Yes. |
| | Surgical instrument for the ear | 78N-1608 | | Yes. |
| | Ear, nose, and throat multiple-use surgical instrument | 78N-1609 | | Yes. |
| | Laryngeal surgical instrument | 78N-1610 | | Yes. |
| | Pharyngeal surgical instrument | 78N-1611 | | Yes. |
| | Nasal and paranasal sinus surgical instrument | 78N-1612 | | Yes. |
| 874.4490 | Microsurgical argon laser [2] | 80P-0501 and 81P-0115 | II, III | |
| 874.4500 | Ear, nose, and throat microsurgical carbon dioxide laser | 78N-1613 | II | Yes. |
| 874.4680 | Bronchoscope (flexible or rigid) and accessories | 78N-1616 | II | |
| | Bronchoscope (flexible or rigid) | 78N-1616 | | Yes. |
| | Ear, nose, and throat endoscopic accessory [3] | 78N-1617 | | Yes. |
| | Laryngeal-bronchial telescope | 78N-1625 | | Yes. |
| 874.4710 | Esophagoscope (flexible or rigid) and accessories | 78N-1619 | II | Yes. |
| 874.4720 | Mediastinoscope and accessories | 78N-1620 | II | Yes. |
| (874.4750) | Laryngostroboscope [1] | 78N-1622 | | |
| | External Laryngostroboscope | 78N-1622 | | No. |
| | Laryngostroboscope (patient-contacting) | 78N-1643 | | Yes. |
| 874.4760 | Nasopharyngoscope (flexible or rigid) and accessories | 78N-1623 | II | Yes. |
| (874.4770) | Otoscope [1] | 78N-1624 | | Yes. |
| 868.5800 (Proposed 874.4800) | Tracheostomy tube and tube cuff | 78N-1626 | II | |
| | Tracheostomy tube | 78N-1626 | | Yes. |
| | Tracheostomy tube cuff | 78N-1626 | | Yes. |
| 868.5795 (Proposed 874.4910) | Tracheal tube cleaning brush | 78N-1627 | I | No. |
| | **SUBPART F—THERAPEUTIC DEVICES** | | | |
| 874.5220 | Ear, nose, and throat drug administration device | 78N-1629 | I | No. |
| (874.5300) | Ear, nose, and throat examination and treatment unit [1] | 78N-1630 | | Yes. |
| 874.5350 | Suction antichoke device | 78N-1597 | III | No. |
| 874.5370 | Tongs antichoke device | 78N-1598 | III | No. |
| (874.5550) | Powered nasal irrigator [1] | 78N-1631 | | Yes. |
| 874.5800 | External nasal splint | 78N-1634 | I | No. |
| 874.5840 | Antistammering device | 78N-1635 | I | Yes. |

[1] Classification postponed.
[2] Not proposed; classification results from reclassification petitions.
[3] The endoscopic accessories formerly identified in this proposed regulation are included in the following sections of the final rule: 874.4680, 874.4710, 874.4720, and 874.4760.

**K. Summaries of Comments and FDA's Responses to Comments**

FDA is responding to comments received on the proposed regulations that were published in the **Federal Register** of January 22, 1982 (47 FR 3280–3325).

1. Comments stated a review of manufacturers' complaint files and of reports in FDA's device experience network show no adverse experience reports for a number of devices. For these reasons, the comments said the devices listed below should be classified into class I, rather than class II or class III as proposed.

| Section | Device | Class proposed, by FDA |
|---|---|---|
| 874.3430 | Middle ear mold | II |
| 874.3450 | Partial ossicular replacement prosthesis. | II |
| 874.3760 | Sacculotomy tack (Cody tack). | II |
| 874.3880 | Tympanostomy tube | II |
| 874.3930 | Tympanostomy tube with semipermeable membrane. | III |

FDA disagrees with the comments regarding the devices above. The reports in FDA's device experience network (DEN) are submitted voluntarily to FDA. FDA believes that the adverse experience reports in DEN and the data in complaint files of manufacturers may not reflect the actual levels of adverse experiences with devices. See the preamble to FDA's reproposed rule on medical device reporting (May 27, 1983; 48 FR 24014 at 24016). In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA published a final rule requiring manufacturers and importers to report to FDA deaths and serious injuries caused or contributed to by devices (See 21 CFR Part 803). FDA believes that the data this reporting system yields are not a definitive basis for classification decisions, as manufacturers need not report adverse experiences which do not rise to the level of death or serious injury, and health professionals are not required to report adverse experiences to manufacturers. Therefore, FDA is classifying the devices listed above into the classes shown.

2. Comments questioned whether the risks to health identified in the proposed regulations for each of the devices listed below justify development of a mandatory performance standard. The comments suggested that these devices be classified into class I, rather than class II as proposed. FDA's responses to these comments are in paragraphs 2a through 2o.

2a. Section 874.1050; Audiometer.

FDA believes that a performance standard is necessary for this device to control calibration parameters, method of calibration, reference levels, test frequencies, distoration level, and masking levels. The agency believes these characteristics must be controlled by a standard to prevent misdiagnosis or injury to the patient resulting from devices of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

2b. Section 874.1060; Acoustic chamber for audiometric testing.

FDA agrees with the comments regarding the acoustic chamber for audiometric testing. FDA now believes that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that labeling that provides adequate directions for use of the acoustic chamber for audiometric testing is sufficient to control the risk to health of asphyxiation. FDA believes that the labeling should provide adequate instructions to the operator and the patient with respect to procedures for opening the door of the acoustic chamber. FDA now believes that it is unnecessary to establish a performance standard for the device. Accordingly, FDA is adopting the proposed regulation with the classification of class I rather than class II as proposed.

2c. Section 874.1080; Audiometer calibration set.

The agency believes that a performance standard is necessary for this device to control calibration parameters to prevent erroneous measurement of hearing thresholds which could lead to a misdiagnosis and to prevent excessive sound output levels from the audiometer which may produce hearing damage in a patient. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

2d. Section 874.1090; Auditory impedance tester.

The agency believes that a performance standard is necessary to control the static pressure produced by the device to prevent damage to the tympanic membrane and to control the sound output levels produced by the device to prevent hearing damage. Accordingly, FDA is adopting the proposed regulation without change.

2e. Section 874.1120; Electronic noise generator for audiometric testing.

The sound output level produced by the device is not under the direct control of the patient, and the patient may tolerate excessive sound levels under the mistaken belief that excessive sound levels are intentional and necessary. The agency believes that a performance standard is necessary to control the maximum sound output levels to minimize the possibility of hearing damage to the patient. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

2f. Section 874.1325; Electroglottograph.

The agency believes that a performance standard is necessary to control the output characteristics of this device to prevent erroneous measurement of electrical impedance of the larynx which could lead to misdiagnosis and subsequent inappropriate therapy. Accordingly, FDA is adopting the proposed regulation without change.

2g. Section 874.1820; Surgical nerve stimulator/locator.

The agency believes that the output characteristics of the surgical nerve stimulator/locator need to be specified and controlled by a performance standard to assure that the electrical current will not damage nerve tissue. The agency notes that application of direct current to an area of exposed nerve may injure the nerve and cause paralysis. A standard is needed to prevent injury to the patient from devices of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

2h. Section 874.3300; Hearing aid.

FDA agrees in part and disagrees in part with the comments urging that the hearing aid be placed in class I instead of class II as proposed. FDA agrees that the air-conduction hearing aid presents a sufficiently low risk to health of hearing loss from excessive sound output levels that the controls of class I, in conjunction with the requirements for labeling and conditions for sale for hearing aids (21 CFR 801.420 and 801.421) would provide reasonable assurance of safety and effectiveness of this kind of hearing aid. However, FDA continues to believe that a performance standard is necessary for the bone-conduction hearing aid to control the sound levels to prevent further hearing damage in a patient and to ensure effectiveness of this kind of hearing aid. A performance standard for the bone-conduction hearing aid would establish the parameters for the values of the data

elements that are required by § 801.420(c)(4) to be included in the labeling and would ensure that each bone-conduction hearing aid device is able to function within such parameters. Accordingly, in the final rule FDA is clarifying the identification of the device, classifying the air-conduction hearing aid into class I, and classifying the bone-conduction hearing aid into class II as proposed.

2i. Section 874.3310; Hearing aid calibrator and analysis system.

The agency believes that a performance standard is necessary for this device to control the accuracy of the calibration mechanism. A standard is needed to minimize erroneous calibration of a hearing aid which could cause further hearing damage in a patient from excessive sound output levels. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

2j. Section 874.3320; Group hearing aid or group auditory trainer.

The agency believes that a performance standard is necessary for this device to control the maximum allowable sound output pressure levels to prevent further hearing damage in a patient. Accordingly, FDA is adopting the proposed regulation without change.

2k. Section 874.3330; Master hearing aid.

The agency believes that a performance standard is necessary for the master hearing aid to control its calibration of a hearing aid, because inaccurate calibration may cause the hearing aid to produce excessive sound output levels and result in further hearing damage in a patient or cause a practitioner to select the wrong hearing aid or incorrectly adjust a hearing aid for a patient. Accordingly, FDA is adopting the proposed regulation without change.

2l. Section 874.3760; Sacculotomy tack (Cody tack).

The agency believes that a performance standard is necessary for the sacculotomy tack to control the size and sharpness of the device and assure its biocompatibility with inner ear tissues and fluids. The agency believes that there is sufficient information available to develop a standard for the device (Ref. 10). Accordingly, FDA is adopting the proposed regulation with minor clarifying changes in the identification of the device.

2m. Section 874.3820; Endolymphatic shunt tube.

FDA believes that a performance standard is necessary to control the risks of possible infection and adverse tissue reaction from the use of materials that are not biologically or mechanically compatible with the body. Implantation of an endolymphatic shunt tube into the middle ear is a major surgical procedure. Accordingly, FDA is adopting the proposed regulation with clarifying changes in the name of the generic type of device and its identification to clarify that the rule also applies to silicone sheets, which serve the same purpose as shunt tubes.

2n. Section 874.3880; Tympanostomy tube.

FDA believes that references 51 through 54 cited in the proposed rule show that performance standards are necessary to control the risks to health, infection and adverse tissue reaction, that are described in the proposed regulation for the device. Further, Reference 11 cited in this final rule shows that large diameter tympanostomy tubes present the additional risk to health of permanent perforation of the tympanic membrane. Thus, to control risks associated with the device, including permanent perforation of the tympanic membrane, adverse tissue reaction, infection, or malleous erosion from devices of improper design or construction (such as use of tubes of excessively large diameter), the agency believes that a performance standard is necessary for the tympanostomy tube. Accordingly, FDA is adopting the proposed regulation with clarifying changes in the identification of the device.

2o. Section 874.5840; Antistammering device.

FDA agrees with the comments suggesting that the antistammering device be classified into class I instead of class II as proposed. FDA now believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is intended for use by persons with normal hearing acuity who have direct control of the sound output levels produced by the device. In case of excessive sound output, the user can either adjust or remove the device. Accordingly, FDA is classifying the device into class I.

3. A comment suggested that the biocompatibility of the devices listed below could be controlled through premarket notification procedures in section 510(k) of the act. The comment suggested that these devices be classified into class I, rather than class II as proposed. No medical or scientific data were presented to support the suggestion.

| Section | Device | Class proposed by FDA |
|---|---|---|
| 874.3695 | Mandibular implant facial posthesis. | II |
| 874.3730 | Laryngeal prosthesis (Taub design). | II |
| 874.3820 | Sacculatomy tack (Cody tack). | II |
| 874.3880 | Tympanostomy tube | II |
| 874.4920 | Tracheostomy tube cuff | II |

FDA disagrees with the comment regarding the devices above. Premarket notification procedures required by section 510(k) of the act and Subpart E of 21 CFR Part 807 apply to manufacturers of a device being introduced into commercial distribution for the first time (as defined in 21 CFR 807.81(a) (1) and (2)) or manufacturers of a commercially distributed device that is about to be significantly changed or modified (as defined in § 807.81(a)(3)). Premarket notification procedures are not intended to assure that preamendments devices and postamendments substantially equivalent devices in commercial distribution are safe and effective. FDA believes that establishment of a performance standard is necessary for each of the devices listed above to control the risks to health identified in the proposed regulations and to provide reasonable assurance of the safety and effectiveness of the devices.

4. Section 874.1100; Earphone cushion for audiometric testing.

A comment stated that premarket notification procedures would be sufficient to detect the use of new materials which may not be biocompatible and cause contact dermatitis. The comment suggested that this device be classified into class I rather than class II as proposed.

FDA agrees with the comment. FDA identified the risk to health of contact dermatitis from use of materials that may not be biocompatible. However, the device is used by a patient for only a short time period. FDA now believes that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is classifying the device in class I.

5. Section 874.3430; Middle ear mold.

Two comments requested that the device be placed in class I instead of class II as proposed, based upon the extensive clinical use of the device with minimal risk to patients.

FDA disagrees with the comments. FDA acknowledges the extensive clinical use over several years of middle ear molds that are implanted in the middle ear. However, the agency notes that the synthetic materials from which

middle ear molds are made have been marketed for less than 10 years. Consequently, there have not been any long-term clinical toxicology studies to determine the biocompatibility of the device at the implantation site. As stated in the proposed regulation, FDA believes that a performance standard is necessary for this device to control the risks to health of adverse tissue reaction and infection, because general controls alone are insufficient to control these risks. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

6. Section 874.3620; Ear, nose, and throat polyamide mesh or foil synthetic polymer material; proposed class II.

A comment requested that the device be classified into class I. No medical or scientific data were presented to support the request.

FDA disagrees with the comment. The agency believes that a performance standard is necessary for this implanted device to control the risks to health of adverse tissue reaction and infection. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

7. FDA proposed that four ear, nose, and throat prostheses be classified into class II if made of certain materials and proposed that the same four devices be classified into class III if made of porous polyethylene.

*Devices Proposed for Class II*

§ 874.3450 Partial ossicular replacement prosthesis
§ 874.3495 Total ossicular replacement prosthesis
§ 874.3620 Ear, nose, and throat polyamide mesh or foil synthetic polymer material
§ 874.3880 Tympanostomy tube

*Devices Proposed for Class III*

§ 874.3465 Porous polyethylene partial ossicular replacement prosthesis
§ 874.3510 Porous polyethylene total ossicular replacement prosthesis
§ 874.3630 Ear, nose, and throat porous polyethylene synthetic polymer material
§ 874.3910 Porous polyethylene tympanostomy tube

During open Panel meetings held on June 22, 1978; November 6, 1978; and March 19, 1979, the Panel recommended that the four devices above made of porous polyethylene (PPE) be classified into class III. At that time, the Panel believed that the general controls of class I alone would not provide sufficient control over the risks to health presented by the four devices intended to be implanted in the ear and that insufficient information was available to develop performance standards for these four devices. Based on the Panel recommendations, FDA prepared draft regulations proposing to classify the four devices made of PPE into class III. These four proposed regulations, accompanied by the other 63 ear, nose, and throat proposed classification regulations, were submitted to FDA's Office of the Commissioner for approval and publication in the **Federal Register**.

On November 3, 1981, the Panel held another public meeting to review additional data on the safety and effectiveness of the four devices. At that meeting, for the reasons set forth below, the Panel recommended that FDA classify each of the four devices made of PPE into class II instead of class III as the Panel had originally recommended. FDA's Center for Devices and Radiological Health then decided to agree with the new recommendations.

However, by the November 3, 1981, advisory committee meeting the draft proposed classification regulations to classify ear, nose, and throat devices had been submitted to FDA's Office of the Commissioner for final approval. Due to inadvertence, the draft proposed regulations were not retrieved and updated to include the results of the November 3, 1981, meeting and the Center's views, both of which now favored a proposed classification into class II. As a result, FDA's proposed classification regulations for ear, nose, and throat devices, published on January 22, 1982, did not include the Panel's November 3, 1981, recommendations that the four PPE devices be in class II or the Center's revised views as to the appropriate classification of the devices.

Although the Panel's class II recommendations were not included in the proposed regulations, FDA received a comment from a manufacturer disagreeing with the Panel's recommendations of November 3, 1981, and requesting that FDA classify the four devices into class III as proposed. FDA also received comments that agreed with the Panel's recommendations of November 3, 1981, that the devices be classified into Class II. These comments requested that FDA classify the four devices into class II instead of class III.

The comment requesting that the four devices be in class III questioned the safety of PPE as an ear implant. The comment noted that the literature on clinical use of PPE in ear surgery did not identify the material in terms of its physical and chemical characteristics. The comment also questioned the effectiveness of PPE as an implant material: the comment questioned the ability of implants made from the material to permit tissue ingrowth and stabilization. The comment summarized the results of a paper by A.G. Kerr (Ref. 6). The comment said that Dr. Kerr, in his examination of 52 patients, did not find evidence that ear implants made of PPE provided tissue ingrowth stabilization.

For the reasons set forth below, FDA now believes that sufficient evidence is available of the safety and effectiveness of the four devices made of PPE that the agency concludes that the four devices should be classified into class II, rather than class III as proposed. FDA believes that the amount of tissue ingrowth into any pores in the implant material is not a critical factor in the agency's determination of whether these implants are placed in class II or class III. FDA is discussing below the critical factors upon which classification of these ear implants is based.

FDA agrees with the comments requesting that FDA classify the four devices made of PPE into class II.

At the meeting of the Panel on March 19, 1979, Dr. Zimlak and Mr. Lurie, American Hoechst Corp., described the process used to produce PPE, the mechanical and chemical properties of PPE, and the use of additives and catalysts in production of PPE. At the same meeting, Mr. Joseph Ferri, General Polymeric Corp., described the procedures used by his company to manufacture PPE. Mr. Ferri said that no additives are used and no chemical changes occur during their conversion of polyethylene (PE) powder to porous polyethylene (PPE).

Although PPE produced through use of various additives may indeed have a different physical and chemical composition from PE, FDA believes that PPE produced without additives (as noted above) can be characterized physically and chemically to the same extent as nonporous PE. Thus, FDA believes that sufficient information is available to develop performance standards for both PE and PPE.

Dr. Shea performed a scanning electron micrograph study of a PPE implant that had been removed from the middle ear of a human patient after it had been implanted for many months (Ref. 8). The study showed interlacing fibrous tissue engaging a section of the PPE implant. Thus, some tissue invasion into the PPE implant does take place from the interlacing network of fibrous connective tissue formed by the body around the implant. The study showed that the result of the tissue invasion is a columna of living tissue with a PPE skeleton. Dr. Shea found no evidence of

either acute or chronic tissue inflammation around the implantation site.

At the Panel meeting of June 22, 1978, Dr. Shea presented data to the Panel on the results of his studies of cats involving implantation of PPE in the middle ear and in the oval window. At this meeting, Dr. Shea also presented results of clinical studies involving 225 PPE implantation procedures in the middle ears of human patients. Data from these procedures were obtained during a followup period of 12 to 28 months. Dr. Shea said that the data showed excellent results. Dr. Shea presented slides to the Panel which illustrated the acceptance of PPE by human tissue and the characteristics of the material that allow tissue ingrowth (Ref. 9).

At the Panel meeting of November 3, 1981, Myron Spector, Ph.D., University of South Carolina, presented data to the Panel on the results of implanting PPE into the middle ear of cats (Ref. 1). The studies showed that after six months of implantation the animal formed a thin fibrous tissue capsule surrounding the implanted PPE material. The fibrous capsule appeared to cover the pores of the implant, and in some areas the fibrous tissue formed a continuum with fibrous tissue within the pores of the PPE material. Dr. Spector stated that internal pores of the PPE contained fibroblasts, blood vessels, macrophages, and foreign body giant cells. Occasionally, the fibroblasts and fibrocollagenous material in the pore structure of the PPE was contiguous with the fibrous capsule itself. The fibrous capsule around the PPE was also seen to be continuous with connective tissue structures of the middle ear. Dr. Spector observed that this fibrous tissue capsule, which formed around the PPE implant, appeared to stabilize the implant in the middle ear.

At the Panel meeting of November 3, 1981, J.M. Cassell and R.E. Dehl, National Bureau of Standards, reviewed the results of their studies performed under contract from FDA to characterize the porosity of PPE (Refs. 2, 3, and 4).

Following its review of the data above, on November 3, 1981, the Panel revised its earlier recommendation. The Panel unanimously recommended that the four ear, nose, and throat devices made of PPE and intended to be implanted in the middle ear be placed in class II. The Panel recommended, however, that the labeling for the four devices made of PPE should indicate that the devices not be implanted in direct contact with fluids of the inner ear.

FDA has concluded that PPE middle ear implants are at least as safe and effective as nonporous PE implants. Sufficient scientific and technical information is available to establish a performance standard that would adequately characterize the PPE material in terms of its physical and chemical specifications. Because the chemical composition of PPE may be different from nonporous PE, FDA believes that PPE should be specified and characterized separately from PE. FDA finds that adequate valid scientific evidence is available to show that middle ear implants made of PPE facilitate, to some extent, tissue ingrowth within the pore structure of the implant that serves to improve overall stabilization of the implant. Data from studies of PPE indicate that a fibrous tissue capsule forms around the implant made of PPE which serves to stabilize the device in a manner similar to the stabilization of the device made of nonporous PE.

Accordingly, FDA is classifying the porous polyethylene partial ossicular replacement prosthesis; porous polyethylene total ossicular replacement prosthesis; ear, nose, and throat porous polyethylene synthetic polymer material; and the porous polyethylene tympanostomy tube into class II instead of class III as proposed. FDA now believes that premarket approval is unnecessary for these four devices, because performance standards established for these devices under section 514 of the act would provide reasonable assurance of the safety and effectiveness of the devices and sufficient information is available to establish such standards. FDA also believes that the general controls of class I alone are insufficient to provide reasonable assurance of the safety and effectiveness of these four devices.

In the final rule, to reduce unnecessary regulations, certain of the devices above have been grouped together. See "D. Grouping of Similar Devices" and "J. List of Ear, Nose, and Throat Devices."

8. Section 874.3850; Endolymphatic shunt tube with valve; proposed class III.

One comment stated that sufficient data are available to assure the safety and effectiveness of the device with establishment of a performance standard. The comment said that the device had been used longer than 7 years and that nearly 2,000 devices had been implanted. The comment alleged that clogging is an infrequent generic problem with endolymphatic tubes, whether valved or not, and that because there is no observable injury to inner ear structures, it is unreasonable to place the valved device in class III. The comment cites clinical data that indicate the following effectiveness rates for the device: relief of vertigo, 89 to 90 percent; hearing stabilization, 64 to 72 percent; relief of aural pressure, 60 to 70 percent; and relief of tinnitus, 35 to 49 percent. The comment recommended that the proper classification of the device should be class I or class II.

FDA disagrees with the comment and believes that the device should be classified into class III as proposed. The agency notes that the endolymphatic shunt tube with valve is a relatively new device that is intended to be implanted. Several different versions have evolved over the past few years. The valve is intended to maintain a physiologically normal endolymphatic pressure, yet little is known about what is normal pressure. If the valve becomes inoperative or clogs, FDA believes that a significant risk to health would result from buildup of fluid pressure in the inner ear. Any surgical procedure to correct a defective valve also presents additional risks to health, such as infection. For these reasons, and the reasons stated in the proposed regulation, the agency believes that the endolymphatic shunt tube with valve should be in class III. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

9. Section 874.3930; Tympanostomy tube with semipermeable membrane; proposed class III.

A comment argued that the risks to health in the proposed regulation are identical to those for the tympanostomy tube that FDA proposed to classify into class II: (a) Perforation; (b) adverse tissue reaction; (c) infection; and (d) hearing loss. Therefore, the comment stated that these risks are not risks which support classification of the tympanostomy tube with semipermeable membrane into class III. Further, the comment noted that hearing loss, as a result of membrane blockage, has not been substantiated in the clinical literature. A second comment stated that, considering the risks to health mentioned in the proposal, a performance standard is adequate to control the safety and effectiveness of the device. The comments recommended that the device be classified into class II, rather than class III as proposed.

FDA disagrees with the comments. The agency believes that the tympanostomy tube with semipermeable membrane presents a significant risk to health that is not presented by other tympanostomy tubes: The risk of hearing

loss due to blockage of the membrane. When the Panel recommended that the device be in class III, data demonstrating the safety and effectiveness of the device were not available (47 FR 3305). The comments did not provide scientific evidence demonstrating that blockage of the membrane is no longer a risk. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

10. Section 874.4140; Ear, nose, and throat bur; proposed class II.

Comments stated that both the physical and material properties of the device and its design have been established for many years. The comments also stated that the cutting device is intended to remove bone and tissue and that the skill of the user is most essential in the safe and effective use of the device. The risks to health of hearing damage from noise or vibration from use next to the cochlea or ossicular chain and of excessive amount of tissue removal are controllable by the user. Eccentricity and corrosion of the device can be detected by the user, and fracture of the device is unlikely to occur. Thus, the comments argued the device should be in class I, rather than class II as proposed.

FDA agrees with the comments. FDA now believes that the general controls of class I will provide reasonable assurance of the safety and effectiveness of the device. FDA believes that manufacturers' adherence to requirements of the current good manufacturing practice (CGMP) regulations in Part 820 would assure that eccentricity of the device is controlled and provide reasonable assurance that it would not fracture during use. Accordingly, FDA is adopting the proposed regulation with a change in classification from class II to class I.

11. Section 874.4250; Ear, nose, and throat electric or pneumatic surgical drill; proposed class II.

A comment stated that the risk to health of mechanical trauma caused by whip or wobble in the device is not appropriate for this generic product as this condition can only occur after attachments are affixed to the device. A comment noted that the risk of noise trauma can be controlled by checking the device for excessive output noise prior to use, and the risk of explosion can be controlled with appropriate labeling concerning use of the device in an explosive atmosphere. A comment stated that general controls would be adequate for this device, because the identified risks to health are user-related, rather than the result of manufacturing deficiencies. The comments suggested that this device be classified into class I rather than class II as proposed.

FDA disagrees with the comments. The agency believes that when the ear, nose, and throat electric or pneumatic surgical drill is being used as intended, the drill would have accessories attached and thus could present the risk of whip or wobble under normal conditions of use. For the reasons stated in the proposal, the agency believes that establishment of a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device, including control of noise output and prevention of fire or explosion when used in the presence of flammable gases. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

12. Section 874.4340; Ear, nose, and throat fiberoptic light source and carrier; proposed class II.

Three comments suggested that electrical hazards alone should not be used as the basis for classifying a device into class II and recommended that this device be classified into class I.

FDA believes that this device should be classified into class II. When the ear, nose, and throat fiberoptic light source and carrier is connected to an used with the various endoscopes for which it is intended, a direct pathway to the thoracic cavity is established that can transmit to the patient any hazardous chassis leakage currents or fault currents. In addition, in FDA's contract problem definition study that identified hazards and performance problems associated with endoscopes and endoscopic accessories (Ref. 12), the contract report recommended that certain performance parameters and attributes of this device be addressed by a standard, such as thermal safety, eye safety, and provisions for back-up lamps. Thus, the device has characteristics other than electrical safety hazard, that warrant a peformance standard. FDA believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and that it is necessary to establish a performance standard to control the attributes identified above to prevent injury to the patient from a device of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

13. FDA proposed to classify the ear, nose, and throat manual surgical instruments listed below into class II. Comments argued that the risks to health identified in these six proposed regulations essentially are the same as the risks identified for the general and plastic surgery manual surgical instruments that FDA proposed to classify into class I. (See § 878.4800 *Manual surgical instrument for general use;* Docket No. 78N–2696; 47 FR 2810; January 19, 1982.) The comments said that a review of complaints received in FDA's device experience network during the last 3 years showed only nine complaints for the manual devices. In each of the nine reports, the device had broken during use. The comments said that these experience data show that the devices do not present risks to health that require performance standards. Comments said that some of the devices also may be included in the identification of the manual surgical instrument for general use (§ 878.4800) that FDA proposed to classify with general and plastic surgery devices. The comments therefore suggested that FDA classify the devices listed below into class I. Further, the comments suggested that the ear, nose, and throat devices listed below, which were subjects of the six separate proposed regulations, be treated as one generic type of device.

| Section | Device | Class proposed by FDA |
|---|---|---|
| 874.4400 | Bronchial, tracheal, or esophageal surgical instrument. | II |
| 874.4410 | Surgical instrument for the ear. | II |
| 874.4420 | Ear, nose, and throat multiple-use surgical instrument. | II |
| 874.4430 | Laryngeal surgical instrument. | II |
| 874.4440 | Pharyngeal surgical instrument. | II |
| 874.4450 | Nasal and paranasal sinus surgical instrument. | II |

FDA agrees that the risks to health identified in the proposed regulations above essentially are the same as the risks identified for general and plastic surgery manual surgical instruments that FDA proposed to classify into class I. FDA agrees that the general controls of class I, particularly the controls of the CGMP regulations in 21 CFR Part 820, would control the risks to health of unnecessary tissue trauma or device fracture and would provide reasonable assurance of the safety and effectiveness of the devices above. The agency now believes that it is unnecessary to establish performance standards for these devices. Accordingly, FDA is classifying the devices above into class I instead of class II as proposed.

FDA disagrees that some of the devices identified above are included in the devices subject to the proposed regulation for general and plastic

surgery manual surgical instruments. Nevertheless, for the reasons given above, FDA now is classifying the devices into class I.

FDA agrees that the devices above should be grouped into one generic type of device. Accordingly, FDA is treating the devices which are subjects of the six proposed regulations listed above as one generic type of device—the ear, nose, and throat manual surgical instrument (§ 874.4420)—and is classifying this device into class I. FDA also is making appropriate changes in the identification of the device.

14. Section 874.4500; Ear, nose, and throat microsurgical carbon dioxide laser; proposed class II.

A comment questioned the need for a performance standard where the possibility of an electrical hazard is involved and suggested that this device be classified into class I rather than class II as proposed. The comment provided no additional data.

FDA disagrees with the comment. The device presents risks other than electrical hazard. The agency believes that the laser beam alignment and exposure characteristics of this device must be controlled by a standard to prevent injury to the patient resulting from devices of improper design or construction. Accordingly, in the final rule FDA is adopting the proposed regulation with clarifying changes in the name and identification of the device.

15. Comments stated that the risks to health FDA identified in the proposed regulations on the devices listed below are unlikely to occur and that these risks can be controlled adequately by the general controls of class I. The comments stated that (1) the risk of tissue trauma due to corrosion or fracture of the devices can be controlled by adequate labeling; (2) electrical hazards can be controlled through appropriate safeguards that have already been established; (3) the risk of trauma as a result of a sharp edge on a device can be controlled with adequate labeling; (4) the risk of asphyxiation due to use of a device of an improper size or shape is the responsibility of the user (given appropriate labeling and sufficient information); (5) the risk of reflex stimulation from the use of a device of an improper size or shape is also within the control of the user; and (6) the risk of infection from a device that is difficult to disassemble, clean, and reassemble or from a device that is not cleaned properly is a function of user knowledge and manufacturers' labeling. The comments also argued that the risk of failure of the ventilation system which may cause the patient to receive an inadequate supply of breathing gas was not considered by FDA to be sufficiently serious to warrant an FDA contract problem definition study to recommend a standard as a solution for this problem. The comments recommended that these devices be classified into class I, rather than class II as proposed.

| Section | Device | Class proposed by FDA |
|---|---|---|
| 874.4680 | Bronchoscope (flexible or rigid) | II |
| 874.4685 | Ear, nose, and throat endoscopic accessory. | II |
| 874.4710 | Esophagoscope (flexible or rigid) | II |
| 874.4720 | Mediastinoscope | II |
| 874.4760 | Nasopharyngoscope (flexible or rigid). | II |

FDA disagrees with the comments. The agency notes that its contract problem definition study, which identified hazards and performance problems associated with endoscopes and endoscopic accessories (Ref. 12), recommended that certain performance characteristics of these devices be addressed by standards (image quality, tip control, protective sheath specifications, control mechanisms, withdrawal mechanisms, brittleness and durability, disassembly procedures, and lamp illumination levels). The agency believes that performance standards are necessary to control these characteristics to prevent injury to the patient resulting from a device of improper design or construction.

FDA proposed that the ear, nose, and throat endoscopic accessory be classified as a separate device. FDA is grouping the accessories that were the subjects of proposed § 874.4685 with each of the respective endoscope devices identified above, as appropriate. Accordingly, FDA is adopting the proposed regulations for the devices listed above with changes in the names of the devices and their identifications to include any accessories.

16. Section 874.4900; Tracheostomy tube; proposed class II.

Comments argued that tissue trauma due to corrosion of a metal tracheostomy tube or fracture of the device is a user's responsibility and that corrosion or fracture may result as a consequence of improper cleaning, improper care, or improper maintenance of the device. The comments recommended this device be classified into class I, rather than class II as proposed.

FDA disagrees with the comments. The agency has reviewed its device experience network reports over the past several years and finds that a significant number of problems have been reported involving tracheostomy tubes (Ref. 13). The agency believes that the general controls of class I are insufficient to control certain risks to health, such as the problems reported in FDA's proposed rule and that these risks can be controlled only by requiring manufacturers to comply with a performance standard for the device. Specific characteristics of the device for which FDA believes that a standard is necessary include integrity of the inflation system and material specifications. Accordingly, FDA is classifying the device into class II as proposed with minor clarifying changes.

### L. Exemptions for Class I Devices

*Exemptions From Current Good Manufacturing Practice (CGMP) Requirements*

Section 513(d)(1)(2)(A) of the act allows FDA to exempt class I devices from certain requirements under the act if the agency determines that compliance with these requirements is not required to assure that the device will be safe and effective and otherwise in compliance with the act. Of the 15 devices FDA is classifying into class I in this rule, FDA is exempting manufacturers of one anesthesiology device and four ear, nose, and throat devices from the CGMP requirements with the exception of the requirements specified in 21 CFR 820.180 and 820.198 relating to records and complaint files. The exemptions apply to the tracheal tube cleaning brush (§ 868.5795), the gustometer (§ 874.1500), the battery-powered artificial larynx (§ 874.3375), the prosthesis modification instrument for ossicular replacement surgery (§ 874.3540), and the ear, nose, and throat drug administration device (§ 874.5220). However, for the reasons given in the preamble to the proposed regulations, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

As stated in the proposed rule, the agency has determined that exemption of manufacturers of any device from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and 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.

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

*Exemptions From the Requirement of Premarket Notification*

FDA proposed to grant an exemption from the requirement of premarket notification for one device, the tracheal tube cleaning brush (proposed § 874.4910). FDA did not receive any comments regarding this proposed exemption. Nor did FDA receive comments urging exemptions for any of the ear, nose, and throat devices subject to other proposed regulations. In this final rule, FDA is granting an exemption from the requirement of premarket notification for the tracheal tube cleaning brush, as proposed. Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification, with limitations, for each four class I ear, nose, and throat devices. The preamble to that proposed rule explained FDA's criteria for granting these exemptions.

**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. Spector, Myron, "Tissue Response to Plastipore and Proplast Otologic Implants in the Middle Ear of Cats," Division of Otolaryngology, Medical University of South Carolina.

2. Dehl, R.E.; Cassell, J. M., "Characterization of Porosity in Porous Polymeric Implant Materials," National Bureau of Standards; Summary minutes; Ear, Nose, and Throat Device Advisory Section meeting, November 2-3, 1981, Appendix J.

3. "Evaluation of Methods of Characterizing the Porosity of Porous Polymeric Implant Materials: A Review of the Current Status of Porosity Measurements," (NBSIR 81-2212), February 1981.

4. "Characterization of Porosity in Porous Polymeric Implant Materials" (NBSIR 81-2459), February 1982.

5. (Reserved)

6. Kerr, A.G., "Proplast and Plastipore," *Clinical Otolaryngology*, 6:187, 1981.

7. (Reserved)

8. Shea, J.J., et al., "Biocompatible Ossicular Implants," *Archives of Otolaryngology*, 104: 191-196, 1978.

9. Shea, J.J., "Porous Polyethylene Information," Shea Clinic; Summary minutes; Ear, Nose, and Throat Device Classification Panel meeting, June 22-23, 1978, Appendix D.

10. Cody, D.T.R., "The Shunt Operation and the Tack Operation, Long-Term Results," *Canadian Journal of Otolaryngology*, 3:3, 271-275, 1974.

11. Holt, J.J., and M.D. Herner, "Effects of Large-Bore Middle Ear Ventilation Tubes," *Journal of Otolaryngology and Head and Neck Surgery*, 88: 581-585, 1980.

12. Skreenock, J.J., D.S. Mead, and J.H. Stalker, "A Study of the Common Characteristic's, Hazards, and Performance Problems of Endoscopes and Endoscopic Accessories," Department of Health and Human Services, FDA Contract Number 223-77-5037, Task Order No. 3, Final Report, ECRI, Plymouth meeting, PA, April 1, 1981.

13. Reports of problems concerning tracheostomy tubes and cuffs, FDA's Device Experience Network, January 1984.

**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**

The Food and Drug Administration has carefully analyzed the economic effects of this final rule and has determined that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, remain subject only to such controls either in their entirety or with certain exemptions. 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 on a substantial number of small entities and are not major rules.

**List of Subjects**

*21 CFR Part 868*

Anesthesiology devices, Medical devices.

*21 CFR Part 874*

Ear, nose, and throat 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 in Parts 868 and 874 as follows:

## PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR Part 868 is revised to read as follows:

**Authority:** Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)); 21 CFR 5.10.

2. Part 868 is amended in Subpart F by adding new §§ 868.5795 and 868.5800 to read as follows:

### Subpart F—Therapeutic Devices

**§ 868.5795 Tracheal tube cleaning brush.**

(a) *Identification.* A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.

(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.

**§ 868.5800 Tracheostomy tube and tube cuff.**

(a) *Identification.* A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) *Classification.* Class II.

3. New Part 874 is added to read as follows:

## PART 874—EAR, NOSE, AND THROAT DEVICES

### Subpart A—General Provisions



### Subpart B—Diagnostic Devices



### Subpart C—[Reserved]

### Subpart D—Prosthetic Devices



### Subpart E—Surgical Devices



### Subpart F—Therapeutic 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

**§ 874.1 Scope.**

(a) This part sets forth the classification of ear, nose, and throat 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 provision 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, an ear, nose, and throat 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.

**§ 874.3 Effective dates of requirement for premarket approval.**

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

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

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of

the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

## Subpart B—Diagnostic Devices

### § 874.1050 Audiometer.

(a) *Identification.* An audiometer or automated audiometer is an electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

(b) *Classification.* Class II.

### § 874.1060 Acoustic chamber for audiometric testing.

(a) *Identification.* An acoustic chamber for audiometric testing is a room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.

(b) *Classification.* Class I.

### § 874.1080 Audiometer calibration set.

(a) *Identification.* An audiometer calibration set is an electronic reference device that is intended to calibrate an audiometer. It measures the sound frequency and intensity characteristics that emanate from an audiometer earphone. The device consists of an acoustic cavity of known volume, a sound level meter, a microphone with calibration traceable to the National Bureau of Standards, oscillators, frequency counters, microphone amplifiers, and a recorder. The device can measure selected audiometer test frequencies at a given intensity level, and selectable audiometer attenuation settings at a given test frequency.

(b) *Classification.* Class II.

### § 874.1090 Auditory impedance tester.

(a) *Identification.* An auditory impedance tester is a device that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of fluid in the middle ear cavity. The device is also used to measure the acoustic reflex threshold from contractions of the stapedial muscle, to monitor healing of tympanic membrane grafts or stapedectomies, or to monitor followup treatment for inflammation of the middle ear.

(b) *Classification.* Class II.

### § 874.110 Earphone cushion for audiometric testing.

(a) *Identification.* An earphone cushion for audiometric testing is a device that is used to cover an audiometer earphone during audiometric testing to provide an acoustic coupling (sound connection path) between the audiometer earphone and the patient's ear.

(b) *Classification.* Class I.

### § 874.1120 Electronic noise generator for audiometric testing.

(a) *Identification.* An electronic noise generator for audiometric testing is a device that consists of a swept frequency generator, an amplifier, and an earphone. It is intended to introduce a masking noise into the non-test ear during an audiometric evaluation. The device minimizes the non-test ear's sensing of test tones and signals being generated for the ear being tested.

(b) *Classification.* Class II.

### § 874.1325 Electroglottograph.

(a) *Identification.* An electroglottograph is an AC-powered device that employs a pair of electrodes that are placed in contact with the skin on both sides of the larynx and held in place by a collar. It is intended to measure the electrical impedance of the larynx to aid in assessing the degree of closure of the vocal cords, confirm larygeal diagnosis, aid behavioral treatment of voice disorders, and aid research concerning the laryngeal mechanism.

(b) *Classification.* Class II.

### § 874.1500 Gustometer.

(a) *Identification.* A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.

(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.

### § 874.1820 Surgical nerve stimulator/locator.

(a) *Identification.* A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

(b) *Classification.* Class II.

### § 874.1925 Toynbee diagnostic tube.

(a) *Identification.* The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.

(b) *Classification.* Class I.

## Subpart C—[Reserved]

## Subpart D—Prosthetic Devices

### § 874.3300 Hearing aid.

(a) *Identification.* A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (§ 874.3320), master hearing aid (§ 874.3330), and tinnitus masker (§ 874.3400).

(b) *Classification.* (1) Class I for the air-conduction hearing aid. (2) Class II for the bone-conduction hearing aid.

### § 874.3310 Hearing aid calibrator and analysis system.

(a) *Identification.* A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. The device consists of an acoustic complex of known cavity volume, a sound level meter, a microphone, oscillators, frequency counters, microphone amplifiers, a distoration analyzer, a chart recorder, and a hearing aid test box.

(b) *Classification.* Class II.

### § 874.3320 Group hearing aid or group auditory trainer.

(a) *Identification.* A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.

(b) *Classification.* Class II.

### § 874.3330 Master hearing aid.

(a) *Identification.* A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for

gain, output, and frequency response. The device is used to select and adjust a person's wearable hearing aid.

(b) *Classification.* Class II.

**§ 874.3375 Battery-powered artificial larynx.**

(a) *Identification.* A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

(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.

**§ 874.3400 Tinnitus masker.**

(a) *Identification.* A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.

(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 § 874.3.

**§ 874.3430 Middle ear mold.**

(a) *Identification.* A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.

(b) *Classification.* Class II.

**§ 874.3450 Partial ossicular replacement prosthesis.**

(a) *Identification.* A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) *Classification.* Class II.

**§ 874.3495 Total ossicular replacement prosthesis.**

(a) *Identification.* A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrance to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.

(b) *Classification.* Class II.

**§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.**

(a) *Identification.* A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper, wire bending die; wire closure forceps; piston cutting jib; gelfoam ™ punch; wire cutting scissors; and ossicular finger vise.

(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.

**§ 874.3620 Ear, nose, and throat synthetic polymer material.**

(a) *Identification.* Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the suregon to conform to the patient's needs. This generic type of device is made of material such as polyamide mesh or foil and porous polyethylene.

(b) *Classification.* Class II.

**§ 874.3695 Mandibular implant facial prosthesis.**

(a) *Identification.* A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.

(b) *Classification.* Class II.

**§ 874.3730 Laryngeal prosthesis (Taub design).**

(a) *Identification.* A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.

(b) *Classification.* Class II.

**§ 874.3760 Sacculotomy tack (Cody tack)**

(a) *Identification.* A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.

(b) *Classification.* Class II.

**§ 874.3820 Endolymphatic shunt.**

(a) *Identification.* An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptons of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. This device is made of polytetrafluoroethylene or silicone elastomer.

(b) *Classification.* Class II.

**§ 874.3850 Endolymphatic shunt tube with valve.**

(a) *Identification.* An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo. The device directs excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. The function of the pressure-limiting inner ear valve is to impede the flow of endolymph so that a physiologically normal endolymphatic pressure is maintained. The device is made of silicone elastomer and polyamide and contains gold radiopaque

markers within the silicone elastomer sheath.

(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 § 874.3.

**§ 874.3880 Tympanostomy tube.**

(a) *Identification.* A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

(b) *Classification.* Class II.

**§ 874.3930 Tympanostomy tube with semipermeable membrane.**

(a) *Identification.* A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

(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 § 874.3.

## Subpart E—Surgical Devices

**§ 874.4100 Epistaxis balloon.**

(a) *Identification.* An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(b) *Classification.* Class I.

**§ 874.4140 Ear, nose, and throat bur.**

(a) *Identification.* An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(b) *Classification.* Class I.

**§ 874.4175 Nasopharyngeal catheter.**

(a) *Identification.* A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(b) *Classification.* Class I.

**§ 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.**

(a) *Identification.* An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (§ 874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

(b) *Classification.* Class II.

**§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.**

(a) *Identification.* An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.

(b) *Classification.* Class II.

**§ 874.4420 Ear, nose, and throat manual surgical instrument.**

(a) *Identification.* An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tub; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tub; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

(b) *Classification.* Class I.

**§ 874.4490 Microsurgical argon laser.**

(a) *Microsurgical argon laser for use in otology*—(1) *Identification.* A microsurgical argon laser for use in otology is a device intended to cut, destroy, or alter tissue or bone of the ear using laser light energy.

(2) *Classification.* Class II.

(b) *Microsurgical argon laser for all other uses*—(1) *Identification.* A microsurgical argon laser for all other uses, including use in laryngology and general use in otolaryngology, is a device that is intended to cut, destroy, or alter tissue.

(2) *Classification.* Class III.

(3) *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 the device identified in paragraph (b) may be commercially distributed. See § 874.3.

**§ 874.4500 Ear, nose, and throat microsurgical carbon dioxide laser.**

(a) *Identification.* An ear, nose, and throat microsurgical carbon dioxide laser is a device intended for the surgical excision of tissue from the ear, nose, and throat area. The device is used, for example, in microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.

(b) *Classification.* Class II.

**§ 874.4680 Bronchoscope (flexible or rigid) and accessories.**

(a) *Identification.* A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

**§ 874.4710 Esophagoscope (flexible or rigid) and accessories.**

(a) *Identification.* An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the esophagoscope and is intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

**§ 874.4720 Mediastinoscope and accessories.**

(a) *Identification.* A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracicly and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

**§ 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.**

(a) *Identification.* A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasosinuscope, nasoscope, postrhinoscope, rhinoscope, salpingoscope, flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biospy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

## Subpart F—Therapeutic Devices

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

(a) *Identification.* An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.

(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.

**§ 874.5350 Suction antichoke device.**

(a) *Identification.* A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.

(b) *Classification.* Class III.

(c) *Date PMA or notice or completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 874.3.

**§ 874.5370 Tongs antichoke device.**

(a) *Identification.* A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A No effective date has been established of the requirement for premarket approval. See § 874.3.

**§ 874.5800 External nasal splint.**

(a) *Identification.* An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.

(b) *Classification.* Class I.

**§ 874.5840 Antistammering device.**

(a) *Identification.* An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitative or repetitive speech.

(b) *Classification.* Class I.

Dated: October 22, 1986.

**Frank E. Young,**

*Commissioner of Food and Drugs.*

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