

beyond the eight-month period specified in paragraph (a) of this section if the following conditions are present:

* * *

PART 773—REQUIREMENTS FOR PERMITS AND PERMIT PROCESSING

7. The authority citation for Part 773 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; 16 U.S.C. 470 *et seq.*; 16 U.S.C. 1531 *et seq.*; 16 U.S.C. 661 *et seq.*; 16 U.S.C. 703 *et seq.*; 16 U.S.C. 668a; 16 U.S.C. 469 *et seq.*; 16 U.S.C. 470aa *et seq.*; and Pub. L. 100-34.

8. Section 773.11 is amended by revising paragraph (a) to read as follows:

§ 773.11 Requirements to obtain permits.

(a) *All operations.* On and after 8 months from the effective date of a permanent regulatory program within a State, no person shall engage in or carry out any surface coal mining operations, unless such person has first obtained a permit issued by the regulatory authority except as provided for in paragraph (b) of this section. A permittee need not renew the permit if no surface coal mining operations will be conducted under the permit and solely reclamation activities remain to be done. Obligations established under a permit continue until completion of surface coal mining and reclamation operations, regardless of whether the authorization to conduct surface coal

mining operations has expired or has been terminated, revoked, or suspended.

* * *

PART 774—REVISION; RENEWAL; AND TRANSFER, ASSIGNMENT, OR SALE OF PERMIT RIGHTS

9. The authority citation for Part 774 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100-34.

10. Section 774.10 is revised to read as follows:

§ 774.10 Information collection.

The collections of information contained in §§ 774.11, 774.13, 774.15 and 774.17 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1029-0088. The information will be used to determine if the applicant meets the requirement for revision, renewal, transfer, sale, or assignment of permit rights. Response is mandatory in accordance with sections 102, 511, 506, and 507 of the Act.

PART 800—BOND AND INSURANCE REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS UNDER REGULATORY PROGRAMS

11. The authority citation for Part 800 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100-34.

12. Section 800.60 is amended by revising paragraph (b) to read as follows:

§ 800.60 Terms and conditions for liability insurance.

* * *

(b) The policy shall be maintained in full force during the life of the permit or any renewal thereof and the liability period necessary to complete all reclamation operations under this Chapter.

* * *

PART 843—FEDERAL ENFORCEMENT

13. The authority citation for Part 843 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100-34.

14. Section 843.11 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 843.11 Cessation orders.

(a) * * *

(2) Surface coal mining operations conducted by any person without a valid surface coal mining permit constitute a condition or practice which causes or can reasonably be expected to cause significant imminent environmental harm to land, air, or water resources unless such operations:

* * *

[FR Doc. 89-8018 Filed 4-4-89; 8:45 am]

BILLING CODE 4310-05-M

THE HISTORY OF THE
CITY OF BOSTON
FROM THE FIRST SETTLEMENT
TO THE PRESENT TIME
BY
JOSEPH NEALE
OF THE BOSTON BAR
IN TWO VOLUMES
VOL. II.
BOSTON: PUBLISHED BY
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Federal Register

Wednesday
April 5, 1989

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 878

**General and Plastic Surgery Devices;
Exemptions From Premarket Notification;
Final Rule**

21 CFR Parts 878 and 892

**Dental and Radiology Devices;
Exemptions From Premarket Notification;
Final Rule and Withdrawal of Proposed
Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 86N-0011]

General and Plastic Surgery Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, eight generic types of class I general and plastic surgery devices. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public.

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Callahan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of safety and effectiveness: class I (general controls), class II (performance standards), and class III (premarket approval).

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for

preamendments devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels specifically included them in recommendations made to the agency. Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification to reduce the number of unnecessary premarket notifications, thereby freeing agency resources for the review of more important notifications.

FDA believes that exempting certain devices from premarket notification will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting devices from the premarket notification program of section 510(k) of the act (21 U.S.C. 360(k)), where premarket notification will not advance FDA's public health mission, will free additional resources to address pressing regulatory concerns and will make the agency more efficient. The development of exemption criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On June 24, 1988 (53 FR 23856), FDA published a final regulation classifying general and plastic surgery devices. Also on June 24, 1988 (53 FR 23880), FDA proposed to exempt from the requirement of premarket notification, with limitations, eight of those class I general and plastic surgery devices. Interested persons were given until August 23, 1988, to comment. One comment was received, and the comment supported FDA's proposal. Accordingly, FDA is adopting the regulation as proposed. The final classification regulation exempted one of the eight devices, the noninflatable extremity splint (§ 878.7910), from certain current good manufacturing practice regulations (53 FR 23856). The amendment to § 878.7910(b) reflects that exemption.

Criteria for 510(k) Exemptions

FDA is exempting a generic type of class I device from the requirement of premarket notification, with the limitations described below, if the agency determines that premarket notification is unnecessary for the protection of the public health. FDA is granting an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (i) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) ensure that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience and relevant reports or studies on device performance. FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use

of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than that in use for the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Reference

The following information has been placed on display 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. "Food and Drug Administration—A Plan for Action Phase II," Public Health Service, Department of Health and Human Services, May 1987, p. 19.

Environmental Impact

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

Economic Impact

FDA has carefully analysed the economic effects of this final rule and has determined that the final rule would 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.

The devices subject to this final rule 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), with certain exemptions.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, Part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR Part 878 continues to read as follows:

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.

2. New § 878.9 is added to Subpart A to read as follows:

§ 878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it has been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

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

§ 878.1800 Speculum and accessories.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

4. Section 878.3250 is amended by revising paragraph (b) to read as follows:

§ 878.3250 External facial fracture fixation appliance.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

5. Section 878.3910 is amended by revising paragraph (b) to read as follows:

§ 878.3910 Noninflatable extremity splint.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to the general requirements concerning records, and § 820.198, with respect to complaint files.

6. Section 878.3925 is amended by revising paragraph (b) to read as follows:

§ 878.3925 Plastic surgery kit and accessories.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

7. Section 878.4160 is amended by revising paragraph (b) to read as follows:

§ 878.4160 Surgical camera and accessories.

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

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

§ 878.4800 Manual surgical instrument for general use.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

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

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

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

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

§ 878.5900 Nonpneumatic tourniquet.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

Dated: February 22, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-8052 Filed 4-4-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 872 and 892

[Docket Nos. 86N-0007 and 86N-0014]

Dental and Radiology Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, 22 generic types of class I dental devices and 4 generic types of class I radiology devices. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission. Granting the exemptions will allow the agency to make better use of its

resources and thus better serve the public. Elsewhere in this issue of the Federal Register, FDA is withdrawing its proposed rules to exempt one dental device and one radiology device.

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT

For dental devices: Gregory Singleton, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7555

For radiology devices: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance and safety and effectiveness: class I (general controls), class II (performance standards), and class III (premarket approval).

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendments devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels specifically included them in recommendations made to the agency. Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of unnecessary premarket notifications, thereby freeing agency resources for the review of more important notifications.

FDA believes that exempting certain devices from premarket notification will allow the agency to make better use of

its resources and thus better serve the public. In other words, the process of exempting devices from the premarket notification program of section 510(k) of the act (21 U.S.C. 360(k)), where premarket notification will not advance FDA's public health mission, will free additional resources to address pressing regulatory concerns and will make the agency more efficient. The development of exemption criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On August 12, 1987 (52 FR 30082), FDA published a final regulation classifying 110 dental devices. Also on August 12, 1987 (52 FR 30120), FDA proposed to exempt from the requirement of premarket notification, with limitations, 23 of those devices classified into class I. Interested persons were given until October 13, 1987, to submit comments on the proposal.

On January 20, 1988 (53 FR 1554), FDA published a final regulation classifying 59 radiology devices. Also on January 20, 1988 (52 FR 1588), FDA proposed to exempt from the requirement of premarket notification, with limitations, six of those devices. Interested persons were given until March 21, 1988, to submit comments on the proposal.

One comment was received on the dental proposal and one comment was received on the radiology proposal. Both comments supported the agency's policy of exempting certain class I devices from the requirement of premarket notification. Accordingly, FDA is adopting the regulations as proposed for 22 dental devices and 4 radiology devices.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice withdrawing the proposed rules to exempt from the requirement of premarket notification one dental device, rubber dam and accessories (§ 872.6300), and one radiology device, wall-mounted radiographic cassette holder (§ 892.1880). After publishing the dental proposal of August 12, 1988, FDA determined that the rubber dam and accessories did not meet its criteria justifying the agency's proposal to exempt the device from premarket notification.

After publishing the radiology proposal, FDA found that it had inadvertently proposed to exempt the wall-mounted radiographic cassette holder, a class II device. Thus, FDA is

withdrawing the proposal to exempt this device.

Further, FDA is postponing publication of a final rule exempting one radiology device, personnel protective shield (§ 892.6500), until the agency has prepared and issued supplementary information to users of the device, such as guidance for improving its labeling.

Criteria for 510(K) Exemptions

FDA is exempting a generic type of class I device from the requirement of premarket notification with the limitations described below, if the agency determines that premarket notification is not necessary for the protection of the public health. FDA may grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (i) be readily detectable by users by visual examination or other means, such as routine testing; e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment, and (c) many changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience and relevant reports or studies on device performance. FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices

within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution of the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than that is used in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Reference

The following information has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 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. "Food and Drug Administration—A Plan for Action Phase II," Public Health Service, Department of Health and Human Services, May 1987, p. 19.

Environmental Impact

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

Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined that the final rule would 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.

The devices subject to this final rule 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), with certain exemptions.

List of Subjects

21 CFR Part 872

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 872 and 892 are amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR Part 872 continues to read as follows:

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.

2. New § 872.9 is added to Subpart A to read as follows:

§ 872.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution of the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it

had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. Section 872.1730 is amended by revising paragraph (b) to read as follows:

§ 872.1730 Electrode gel for pulp tester.

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

4. Section 872.1905 is amended by revising paragraph (b) to read as follows:

§ 872.1905 Dental X-ray film holder.

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

5. Section 872.3080 is amended by revising paragraph (b) to read as follows:

§ 872.3080 Mercury and alloy dispenser.

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

6. Section 872.3110 is amended by revising paragraph (b) to read as follows:

§ 872.3110 Dental amalgam capsule.

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

7. Section 872.3140 is amended by revising paragraph (b) to read as follows:

§ 872.3140 Resin applicator.

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

8. Section 872.3150 is amended by revising paragraph (b) to read as follows:

§ 872.3150 Articulator.

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

9. Section 872.3220 is amended by revising paragraph (b) to read as follows:

§ 872.3220 Facebow.

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

10. Section 872.3830 is amended by revising paragraph (b) to read as follows:

§ 872.3830 Endodontic paper point.

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

11. Section 872.3840 is amended by revising paragraph (b) to read as follows:

§ 872.3840 Endodontic silver point.

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

notification procedures in Subpart E of Part 807 of this chapter.

12. Section 872.3850 is amended by revising paragraph (b) to read as follows:

§ 872.3850 Gutta percha.

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

13. Section 872.4565 is amended by revising paragraph (b) to read as follows:

§ 872.4565 Dental hand instrument.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

14. Section 872.6010 is amended by revising paragraph (b) to read as follows:

§ 872.6010 Abrasive device and accessories.

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

15. Section 872.6050 is amended by revising paragraph (b) to read as follows:

§ 872.6050 Saliva absorber.

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

16. Section 872.6200 is amended by revising paragraph (b) to read as follows:

§ 872.6200 Base plate shellac.

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

17. Section 872.6290 is amended by revising paragraph (b) to read as follows:

§ 872.6290 Prophylaxis cup.

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

18. Section 872.6390 is amended by revising paragraph (b) to read as follows:

§ 872.6390 Dental floss.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

19. Section 872.6570 is amended by revising paragraph (b) to read as follows:

§ 872.6570 Impression tube.

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

20. Section 872.6650 is amended by revising paragraph (b) to read as follows:

§ 872.6650 Massaging pick or tip for oral hygiene.

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

notification procedures in Subpart E of Part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

21. Section 872.6670 is amended by revising paragraph (b) to read as follows:

§ 872.6670 Silicate protector.

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

22. Section 872.6855 is amended by revising paragraph (b) to read as follows:

§ 872.6855 Manual toothbrush.

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

23. Section 872.6870 is amended by revising paragraph (b) to read as follows:

§ 872.6870 Disposable fluoride tray.

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

24. Section 872.6880 is amended by revising paragraph (b) to read as follows:

§ 872.6880 Preformed impression tray.

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

PART 892—RADIOLOGY DEVICES

25. The authority citation for 21 CFR Part 892 continues to read as follows:

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.

26. New § 892.9 is added to Subpart A to read as follows:

§ 892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal

blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

27. Section 892.1370 is amended by revising paragraph (b) to read as follows:

§ 892.1370 Nuclear anthropomorphic phantom.

* * *

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

28. Section 892.1380 is amended by revising paragraph (b) to read as follows:

§ 892.1380 Nuclear flood course phantom.

* * *

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

29. Section 892.1400 is amended by revising paragraph (b) to read as follows:

§ 892.1400 Nuclear sealed calibration source.

* * *

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

notification procedures in Subpart E of Part 807 of this chapter.

30. Section 892.1420 is amended by revising paragraph (b) to read as follows:

§ 892.1420 Radionuclide test pattern phantom.

* * *

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

Dated: February 22, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

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