

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 872, 878, 880, 882, 884, and 892

[Docket No. 01N-0073]

DMB

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Certifier	<i>[Signature]</i>

Medical Devices; Exemption From Premarket Notification Requirements; Class I Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: In the **Federal Register** of July 25, 2001 (66 FR 38786), the Food and Drug Administration (FDA) amended its medical device classification regulations for class I devices to specifically add a reference to the general limitations on exemptions from premarket notification requirements from each generic device classified as exempt in each section. As published, an exemption from the premarket notification requirements and a reference to the general limitations language was inadvertently added to 12 device classifications that should not include the reference. These devices are not exempt from the requirements of premarket notification. This document corrects those errors.

DATES: This rule is effective [*insert date of publication in the Federal Register.*]

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Background

Provisions under section 206 of the Food and Drug Administration Modernization Act (FDAMA) exempt certain class I devices from the premarket notification requirements of the

Federal Food, Drug, and Cosmetic Act (the act). To implement the new law, FDA evaluated all class I devices to determine which device types should become exempt under the new provisions and which device types should remain subject to the requirements of 510(k) of the act (21 U.S.C. 360(k)). FDA then amended its classification regulations through a series of publications in the **Federal Register** (63 FR 63222, November 12, 1998; 65 FR 2296, January 14, 2000; 63 FR 5387, February 2, 1998; and 66 FR 38786). The most recent amendment (66 FR 38786) revised statutory citations for over 500 devices in order to reference the limitation provisions found in each device classification regulation for devices that were exempt from the premarket notification requirements for clarity and convenience. During preparation of the final rule, however, certain devices were inadvertently included in a list of devices to be amended, and were erroneously changed by adding the limitations language and an exemption from premarket notification. This document corrects those errors.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

III. Analysis of Impacts

FDA has examined the impact of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive order. In

addition, this rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not change the status quo for these devices, the agency certifies that this final rule will not have a significant negative economic impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Parts 872, 878, 880, 882, and 884

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, 21 CFR parts 872, 878, 880, 882, 884, 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: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.6710 is amended by revising paragraph (b) to read as follows:

§ 872.6710 Boiling water sterilizer.

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

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

4. Section 878.4460 is amended by revising paragraph (b) to read as follows:

§ 878.4460 Surgeon's glove.

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

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

6. Section 880.5680 is amended by revising paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

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(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180,

with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

7. Section 880.6250 is amended by revising paragraph (b) to read as follows:

§ 880.6250 Patient examination glove.

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

8. Section 880.6375 is amended by revising paragraph (b) to read as follows:

§ 880.6375 Patient lubricant.

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

9. Section 880.6760 is amended by revising paragraph (b) to read as follows:

§ 880.6760 Protective restraint.

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

PART 882—NEUROLOGICAL DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

11. Section 882.1030 is amended by revising paragraph (b) to read as follows:

§ 882.1030 Ataxiagraph.

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

12. Section 882.1420 is amended by revising paragraph (b) to read as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

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

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

13. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

14. Section 884.2980 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2980 Telethermographic system.

(a) * * *

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

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15. Section 884.2982 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) * * *

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

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PART 892—RADIOLOGY DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

17. Section 892.1100 is amended by revising paragraph (b) to read as follows:

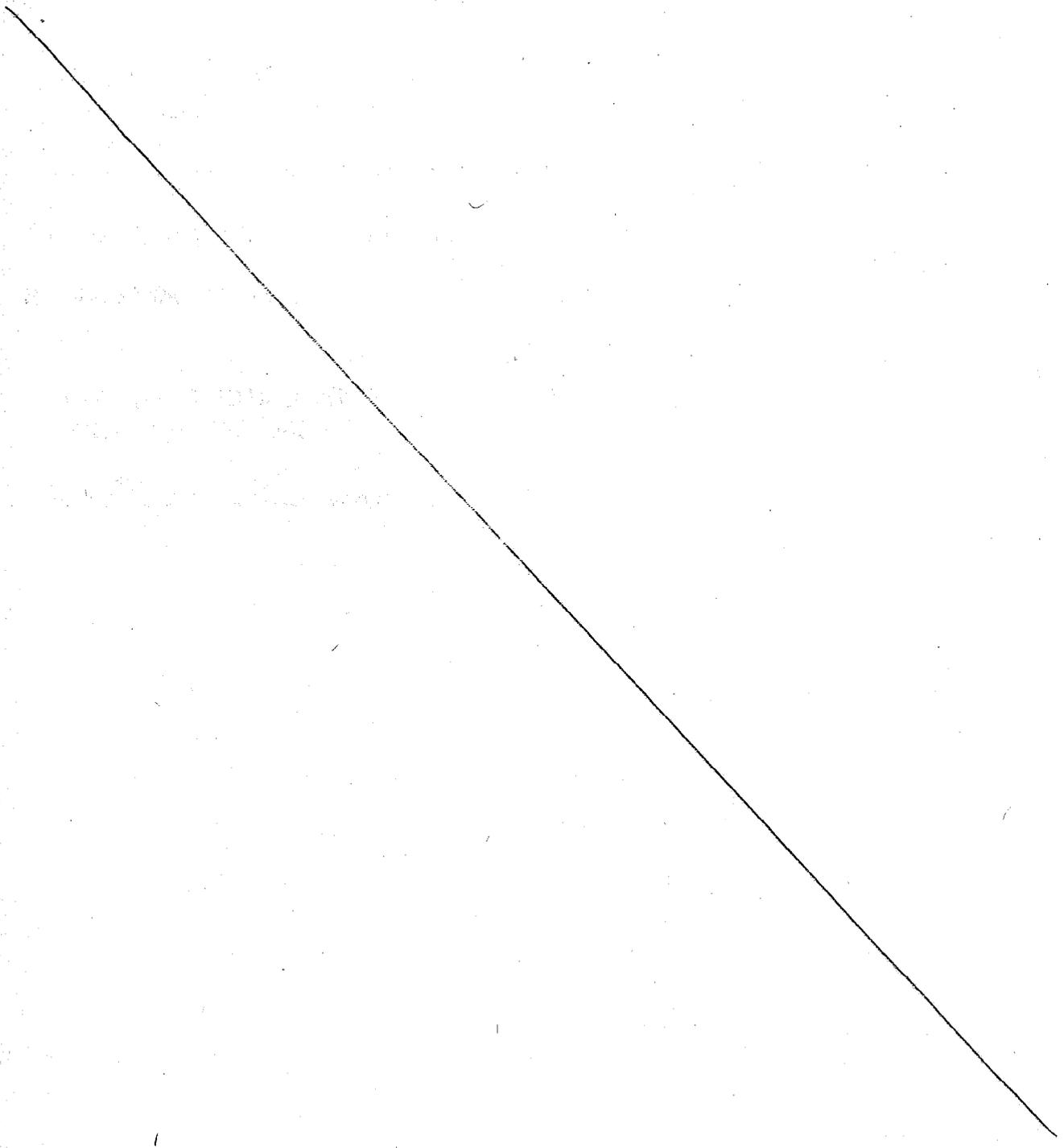
§ 892.1100 Scintillation (gamma) camera.

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

18. Section 892.1110 is amended by revising paragraph (b) to read as follows:

§ 892.1110 **Positron camera.**



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

Dated: 8/23/01
August 23, 2001.

Linda S. Kahan

Linda S. Kahan,
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Regina Lederman