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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N-0786]

General Hospital and Personal Use Devices; Classification of Liquid Chemical Sterilants/High Level Disinfectants and General Purpose Disinfectants

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying liquid chemical sterilants/high level disinfectants intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use into class II (special controls), and general purpose disinfectants intended to process noncritical medical devices and equipment surfaces into class I (general controls). FDA is also exempting the general purpose disinfectants from the premarket notification requirements. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (the FDMA).

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (CDRH) (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

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NFR 1

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and the FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f))) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application

(PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the General Hospital and Personal Use Devices Panel (the Panel), an FDA advisory committee, regarding the classification of these devices.

The FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as “reserved criteria.” FDA has considered the general purpose disinfectants in accordance with the reserved criteria and determined that these devices do not require premarket notification. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

II. Regulatory History of the Device

In the **Federal Register** of November 6, 1998 (63 FR 59917), FDA proposed to classify both liquid chemical sterilants intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use into class II and general purpose disinfectants intended to process noncritical medical devices and equipment surfaces into class I. In the same issue of the **Federal Register**, FDA proposed to exempt the general purpose disinfectants from the premarket notification requirements. FDA recognizes a “high level disinfectant” as a potential separate or subordinate condition of use of a sterilant and has included it in the final rule to clarify its classification status. Initially, interested persons were given until February 4, 1999, to comment on the proposed regulation. Subsequently, FDA extended the comment period to March 8, 1999, in response to an extension request.

FDA received one comment on the proposed rule from a non-profit trade association.

III. Summary of Final Rule

As required by 21 CFR 860.84(g)(1) of the regulations, FDA is classifying liquid chemical sterilants/high level disinfectants into class II with the following special controls: The 510(k) guidance document (Ref. 1) and user information and training. FDA is also classifying general purpose disinfectants into class I and exempting these devices from premarket notification.

Persons interested in obtaining a copy of the guidance (Ref. 1) may do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. “Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants” available at <http://www.fda.gov/cdrh/ode/397.pdf>.

IV. Analysis of Comment and FDA’s Response

The one comment FDA received requested that general purpose disinfectants, in addition to being exempt from the premarket notification procedures, also be exempt from the good manufacturing practice (GMP) requirements set forth in the Quality System Regulation (21 CFR part 820). The comment stated that general purpose disinfectants should be exempt from the GMP requirements because the Environmental Protection Agency (EPA) and state controls on them are sufficient to assure their quality for commercial distribution.

FDA disagrees with the comment. The agency recognizes the dual regulatory functions and responsibilities of the FDA and EPA, but the functions and responsibilities of these agencies address different aspects of the product. Because of the continued classification of the general purpose disinfectants as a medical device, they remain subject to the GMP requirements of the act.

General purpose disinfectants are also regulated by EPA as environmental pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA controls (EPA product registration, Good Laboratory Practices, State registration and testing, maintenance of records, and EPA establishment registration) focus on the quality and integrity of pesticide data. Although some

States have programs regulating the sale and use of general purpose disinfectants as pesticides, not all States have adopted the same enforcement programs. This lack of uniformity does not provide the additional safeguard needed for the national use of these products for disinfection of medical devices.

Therefore, under section 513 of the act, FDA is adopting the summary of reasons for the Panel's recommendation and the summary of data upon which the Panel's recommendation is based, in their entirety. FDA also agrees with the assessment of the risks to public health stated in the proposed rule published on November 6, 1998. FDA is issuing this final rule, which classifies these generic types of devices as follows: Liquid chemical sterilants/high level disinfectants into class II and general purpose disinfectants into class I.

V. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, "Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants," January 3, 2000.

VI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final 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 Enforcement 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The classification of these devices formalizes the current process for the class I and II devices. For the class I devices, FDA is not adding any additional burden, because they are effectively regulated as class I devices now. For the class II devices, they are in compliance with the guidance. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

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

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

2. Section 880.6885 is added to subpart G to read as follows:

§ 880.6885 Liquid chemical sterilants/high level disinfectants.

(a) *Identification.* A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin.

(b) *Classification.* Class II (special controls). Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants, and user information and training.

3. Section 880.6890 is added to subpart G to read as follows:

§ 880.6890 General purpose disinfectants.

(a) *Identification.* A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: 5/23/00
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Linda S. Kahan,
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

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