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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

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Certifier A. Corbin

[Docket No. 01N-0339]

Medical Devices; Classification for Medical Washer and Medical Washer-Disinfector

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the medical washer and medical washer-disinfector intended for general medical purposes to clean and dry surgical instruments, decontaminate or disinfect anesthesia equipment, hollowware, and other medical devices into class II (special controls). FDA is also identifying the guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors" (the guidance) as the special control that, in addition to general controls, the agency believes will reasonably ensure the safety and effectiveness of the device. 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 FDAMA).

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

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

SUPPLEMENTARY INFORMATION:

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) 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 this device.

II. Regulatory History of the Device

In the **Federal Register** of February 7, 2002 (67 FR 5750), FDA proposed to classify the medical washer and medical washer-disinfector into class II (special controls). This device is intended for general medical purposes to clean and dry surgical instruments, decontaminate or disinfect anesthesia equipment, hollowware, and other medical devices.

Interested persons were given until May 8, 2002 to comment on the proposed regulation.

FDA received a total of three comments from one health professional, a consumer group, and one consumer. All three comments agreed with the

proposed rule. In addition, one comment suggested that FDA require manufacturers to include testing to monitor cleaning efficacy.

III. Summary of Final Rule

FDA believes that in order to reduce the potential for confusion, the identification terms “general use” washer and “general use washer-disinfector” as recommended by the Panel should be changed to “medical washer” and “medical washer-disinfector.” The new terms will distinguish these devices from “general purpose article” washers and washer-disinfectors that are exempt from section 510(k) of the act requirements. FDA also believes that decontamination and disinfection are distinct intended uses that require FDA to distinguish washers from washer-disinfectors in classification descriptions.

FDA concurred with the Panel that the medical washers and washer-disinfectors should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. FDA identified the guidance entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors” as the special control for these devices. Following the effective date of this final classification rule, any firm submitting a section 510(k) of the act premarket notification for a medical washer or medical washer disinfector will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

As the Panel initially recommended, FDA believes that the medical washer is exempt from section 510(k) of the act requirements and that some medical

washer-disinfectors can also be exempt from section 510(k) of the act requirements, depending on intended use. The medical washer-disinfector intended to clean and provide high level disinfection to medical devices should be subject to section 510(k) of the act requirements because the reusable devices subject to a high level disinfection process may pose a high risk of infection and other serious sequelae if the washer-disinfector is unsafe or ineffective. The medical washer-disinfector intended to clean and provide low or intermediate level disinfection can be exempt from 510(k) requirements because the reusable devices subject to low or intermediate disinfection pose a relatively lower risk of infection and other serious sequelae if the washer-disinfector is unsafe or ineffective.

In order to receive the guidance entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors” via your fax machine, call the CDRH Facts-on-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1252) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also 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 Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on

video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The document entitled "Class II Special Controls Guidance Document: Medical Washer and Medical Washer-Disinfector" is available on the Internet at <http://www.fda.gov/cdrh/ode/guidance/1252.pdf>.

IV. Analysis of Comments and FDA's Response

FDA received three comments. All three comments agreed with the classification. One comment also suggested that FDA require manufacturers to include testing to monitor cleaning efficacy.

Currently, there is no standard for validating cleaning efficacy. Manufacturers can include in their manuals recommendations for routine monitoring of cleaning efficacy and frequency of testing. The guidance document does not prevent them from doing this. Once standardized test methods are available, FDA will review and recognize those standardized test methods as appropriate.

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 its entirety. FDA is also adopting the assessment of the risks to public health stated in the proposed rule published on February 7, 2002. Furthermore, FDA is issuing this final rule that classifies the generic type of device, medical washer and medical washer-disinfector into class II.

V. 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.

VI. 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), 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 special controls guidance document does not impose any new burdens on these or future manufacturers. It merely assures that, in the future, devices of this generic type will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document merely advises manufacturers on appropriate means of complying with these requirements. 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required.

The information collections addressed in the special control guidance document identified by this rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions, 21 CFR part 807, subpart E, OMB control number 0910–0120.

IX. Reference

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

1. Transcript of General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting, September 14, 1998.

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 880.6991 is added to subpart G to read as follows:

§ 880.6991 Medical washer.

(a) *Identification.* A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.” The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

3. Section 880.6992 is added to subpart G to read as follows:

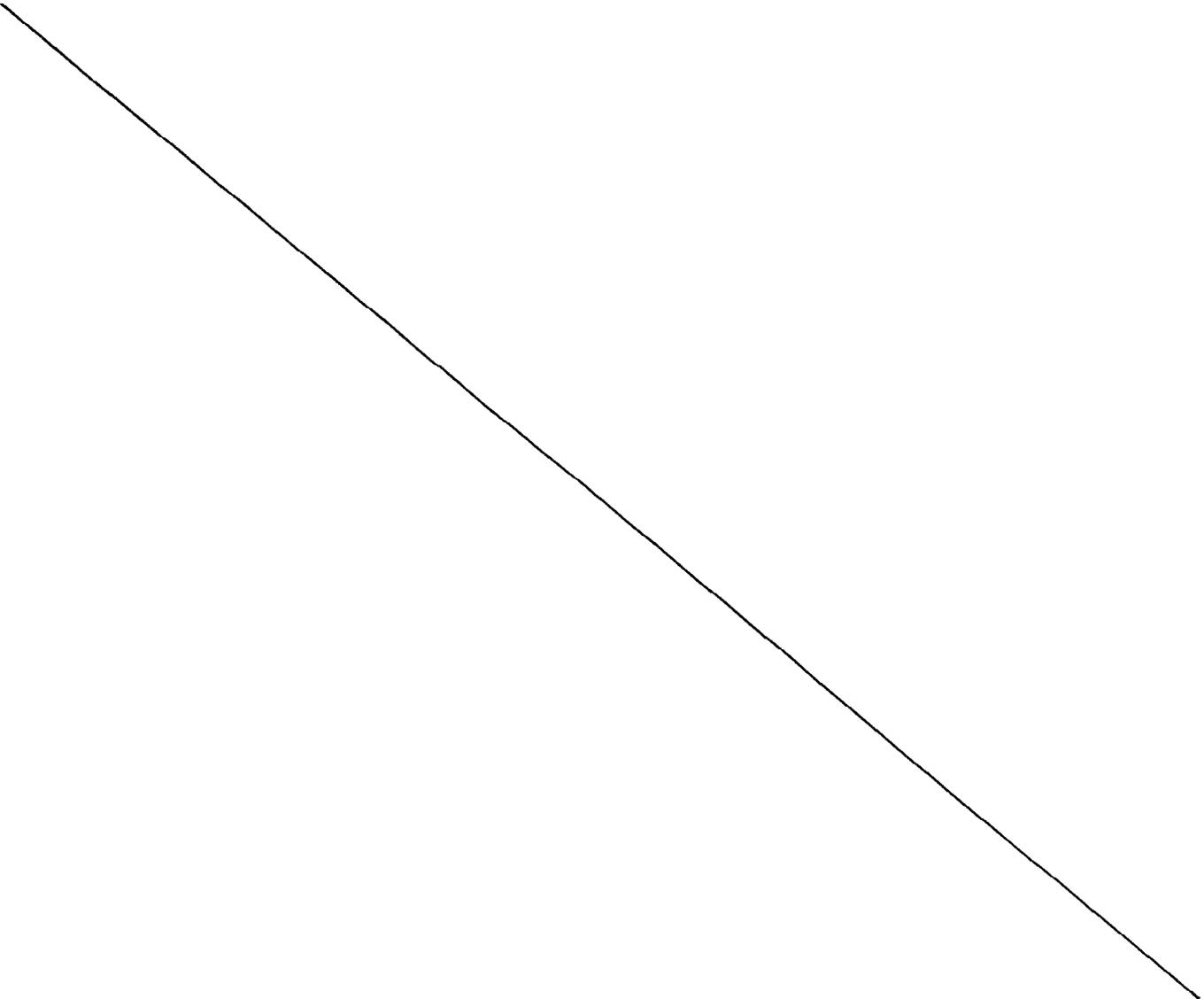
§ 880.6992 Medical washer-disinfector.

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry

surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.”

(1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.



(2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

Dated: 10/28/02
October 28, 2002.

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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