Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff

This guidance supercedes "Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer-Disinfectors," November 5, 1998.

Published on February 7, 2002

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Infection Control Devices Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document and Docket No. 98D-0729. Comments may not be acted upon by the Agency until the document is next revised or updated

For questions regarding the use or interpretation of this guidance contact Chiu S. Lin, Ph.D. at 240-276-3700 or by electronic mail at chiu.lin@fda.hhs.gov.

Additional Copies:

Additional copies are available from the Internet on the CDRH home page: http://www.fda.gov/cdrh/ode/guidance/1252.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (1252) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

TABLE OF CONTENTS

Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Forward

On February 7, 2002, FDA issued a proposed rule to classify medical washers and medical washer-disinfectors into class II and establish this guidance document as a special control for these devices. This guidance document will not take effect as a special control until FDA issues a final rule classifying the device into class II.

This special control guidance was developed by the Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Devices (DDIGD), Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA).

A medical washer or washer-disinfector is a medical device intended to process medical devices. The FDA regulates the introduction of medical devices in interstate commerce. A medical washer-disinfector intended to clean and provide high level disinfection of medical devices must have a FDA cleared premarket notification [510(k)] submission before it can be sold. A medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either low or intermediate level disinfection of medical devices is exempt from 510(k) requirements. Regulations governing the general content and format of 510(k) submissions are codified under 21 Code of Federal Regulations, Part 807. Regulatory requirements pertaining to the marketing of a new medical device are available from the CDRH Division of Small Manufacturers Assistance (DSMA).

The intent of this document for Class II Medical Washers and Medical Washer-Disinfectors is: (1) to provide applicants specific directions regarding information and data that should be submitted to the FDA in a 510(k) submission for medical washer-disinfectors intended to clean and provide high level disinfection and (2) to provide recommendations on information and data to be held as part of the design control record for a medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either a low or intermediate level of disinfection for medical devices.

The FDA believes that a safe and effective system for cleaning and disinfecting medical devices is important in protecting the public health. Washers and washer-disinfectors impact infection control in two areas: (1) when the medical washer-disinfector is used as the terminal process and (2) when the medical washer or washer-disinfector is used as one of the steps prior to a terminal process. Thus, comprehensive and scientifically sound criteria are essential to ensure that these devices are safe and effective for their intended use when used according to their labeling. It is therefore the aim of this document to provide manufacturers with the agency's recommendations for 510(k) submissions and design control records pertaining to these devices.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

I. Introduction

A. Scope

1. This document is a special control guidance for Class II medical washers and medical washer-disinfectors intended to process medical devices.

2. The guidance applies to medical washers and medical washer-disinfectors, which are electromechanical and microprocessor controlled. Medical washers utilize a mechanical process to physically remove contamination from devices while medical washer-disinfectors also have a separate disinfection step, which can be either thermal or chemical.

3. The intended uses within the scope of this guidance include:

    a. Medical washer: A device intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware and other medical devices.

    b. Medical Washer-Disinfector: A device intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical

instruments, anesthesia equipment, hollowware and other medical devices.

4. Exclusion: This document does not address manual cleaning accessories, such as brushes, buckets, etc. This document is not intended to replace the guidance for washers and washer-disinfectors dedicated to specific devices, such as flexible endoscopes.

B. Purpose

This guidance is intended to:

1. Assist persons (manufacturers, distributors, or importers) in the organization and preparation of 510(k) submissions and design control documents for medical washers and washer-disinfectors;

2. Achieve consistency in meeting the requirements and in the presentation of information; and

3. Guide FDA review staff in conducting and documenting the review of 510(k) submissions.

C. Definitions

1. Bioburden (microbial load): The number and type of viable microorganisms with which an item is contaminated; also known as "bioload" or "microbial load." When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item (AAMI, 1995).

2. Cleaning: The physical removal of organic material or soil from objects, usually done by using water with or without detergents. Generally, cleaning is designed to remove rather than to kill microorganisms (Garner, 1985).

3. Decontamination: According to the Occupational Safety and Health Administration (OSHA), "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29 CFR 1910.1030]. In common usage, "decontamination" generally refers to all pathogens (microorganisms capable of producing disease or infection), not just those transmitted by human blood (AAMI, 1995).

   "Decontamination" is an infection control term that can be applied to the reprocessing of medical devices. While the cleaning and disinfection terms have

specific quantitative endpoints, decontamination is a nonspecific, qualitative term that can relate to many different types or degrees of reprocessing and that is part of the reprocessing scheme to ensure safe handling and transport prior to a terminal process.

4. Disinfectant: An agent that eliminates a defined scope of pathogenic organisms, but not necessarily all microbial forms (e.g., bacterial endospores) (Rutala, 1990).

5. Disinfection: The destruction of pathogenic and other kinds of microorganisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, because it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes (AAMI, 1995).

6. Germicide: An agent that destroys microorganisms, especially pathogenic organisms. Other terms with the suffix -cide (e.g., virucide, fungicide, bactericide, sporicide, tuberculocide) destroy the microorganism identified by the prefix (Block, 1991).

7. High Level Disinfectant: A disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores, when used according to labeling (Rutala, 1990; Spaulding, 1971, 1972).

8. Inorganic and Organic Load: The naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device prior to exposure to a microbicidal process.

9. Intended Use: It is the objective intent of the persons legally responsible for labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. (21 CFR 801.4).

10. Intermediate Level Disinfectant: A disinfectant that is effective against viruses, mycobacteria, fungi, and vegetative bacteria, but not bacterial spores when used according to labeling. (Labeling Reusable Medical Devices for Reprocessing In Health Care Facilities: FDA Reviewer Guidance, April 1, 1996).

11. Low Level Disinfectant: A disinfectant that is effective against vegetative forms of bacteria, some fungi, and lipid viruses when used according to labeling. (Labeling Reusable Medical Devices for Reprocessing In Health Care Facilities:

FDA Reviewer Guidance, April 1, 1996).

12. Medical Device (as defined by the Federal Food, Drug, and Cosmetic Act): An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

13. Medical Washer: A medical device intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

14. Medical Washer-Disinfector: A medical device intended for general medical purposes to clean, decontaminate or disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

15. Process Residue: The substance remaining on a medical device after exposure to a cleaning, disinfection, or terminal sterilization process.

16. Spore (or endospore): The dormant state of an organism, typically a bacterium or fungus, which exhibits a lack of biosynthetic activity, reduced respiratory activity, and has resistance to heat, radiation, desiccation, and various chemical agents.

17. Unit: A specified substrate or carrier upon which a specified number of test organisms are inoculated. A unit may be a specified volume, weight, or surface area. For example, a unit could be specified as an entire device or a component of a device (if the device must be disassembled prior to processing), or a portion of a device.

18. Validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled (21 CFR 820.3).

19. Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (21 CFR 820.3).

20. Worst Case Condition: An extreme state such as for a parameter, variable, test, or operating environment.

D. Principles Regarding Data Presentation for a 510(k) Submission

Note: The following information is primarily applicable to the 510(k) submission. A manufacturer of a medical washer or medical washer-disinfector exempt from 510(k) requirements may find it useful to consider these recommendations for its design control records.

1. Editorial Considerations: Manufacturers should carefully edit all documents to assure that all pages/sections are included and are properly indicated, consecutive, distinctly copied, and legible.

2. Abbreviations: All abbreviations should be identified at the beginning of each section in which they are used or in footnotes to tables and graphs.

3. Data Availability: This document outlines typical circumstances of data review. It is not possible to anticipate all situations that may require FDA review. Thus, persons submitting 510(k) submissions should be aware that they may be asked to submit additional data, to present data in another format, or to provide more detailed explanations of the information submitted to establish substantial equivalence.

   Manufacturers should keep data used for design control purposes on file in a controlled and well-organized format. This will allow the manufacturer to supply FDA with additional information or analysis if required. Errors in data that are identified after any submission should be brought to FDA's attention immediately.

4. Tables and Graphs: All tables should be titled and captioned with symbols keyed to a footnote or an accessible reference page that adequately indicates the nature of the data. Graphs should supplement, not replace, data tables.

5. Published Literature: Published methods or data referenced in study reports should be appended to the study report. Reprints of other referenced published reports or data should be appended to the section in which they are referenced. For 510(k) submissions, all referenced reports and data should be summarized with explanations of how they relate to the current submission. References should be complete (e.g., title, author, journal, volume, year).

6. Protocols and Data Analysis: Test reports should include the full protocol and a summary of the critical aspects (objectives, precise description of materials, experimental methods, controls, observations, statistical methods and analyses, conclusions, and comments). Additional specific directions on protocols are included in the sections that follow.

7. Reference to Submitted Data: For a medical washer-disinfector, refer to any information previously submitted to the FDA in support of the 510(k). Provide the relevant information, or have the original submitter provide a letter of authorization to FDA. Often, if the data are not extensive, resubmitting data in the 510(k) will facilitate the review of the document.

8. Other Considerations:

   a. 510(k) submissions should include a response to all elements in Part II below, or include an explanation as to why the data or certain particular information have not been supplied, or why alternative information is justified. Original 510(k)s that are grossly incomplete following cursory review will be immediately deleted with notification to the person.

   b. A single 510(k) submission will suffice for a common product group, such as medical washer-disinfectors with the same processing cycles but different sized processing chambers. Other device differences may require submissions as separate 510(k)s and will be considered on a case by case basis.

   c. Under Section 807.87(h), a person may amend a 510(k) to include additional information requested by FDA that is necessary to reach a finding as to whether the device is substantially equivalent to a legally marketed device. The FDA may notify persons by telephone and/or in writing of needed information. The FDA will normally use telephone contact to clarify minor deficiencies. Once the FDA notifies a person of deficiencies, the 510(k) will be placed on hold. The person may elect to do one of the following:

      (1) provide the requested information;

      (2) formally withdraw the 510(k) submission or;

      (3) allow the submission to be withdrawn administratively.

      The FDA will administratively withdraw a submission after 30 days if FDA does not receive a response to a request for information. The person may request an extension of the 30-day response period by

submitting a written request for an extension to the Document Mail Center, clearly indicating the assigned 510(k) number and the additional time needed. The time period for the extension is not open-ended and will be determined on a case by case basis. If the deficiencies are such that the FDA believes a firm cannot respond completely within 30 days, the FDA will immediately delete the 510(k) with notification to the person.

Responses to FDA letters or telephone calls requesting additional information should be submitted in writing to the Document Mail Center. The supplemental information should clearly indicate the assigned 510(k) number and include a restatement of the deficiencies (or append a copy of the deficiency letter) and a complete response. The additional information is considered a supplement to the 510(k). A grossly incomplete response to a request for additional information will not be evaluated in detail, and the FDA may place the file on hold again after the person is notified. A less than comprehensive response may also raise new questions, which will need to be addressed. Therefore, in order to minimize review iterations, the person should respond fully to the request for information.

d. The FDA recommends that nonclinical laboratory studies for the medical washer or medical washer-disinfector be conducted according to GLP regulations, 21 CFR Part 58. Compliance with GLP regulations will help to ensure the quality and integrity of the data.

E. Device Modifications Requiring a New 510(k) Submission

21 CFR 807.81 specifies that a 510(k) submission is required when significant modifications that could affect safety and effectiveness are made to a 510(k) cleared device. A 510(k) is also required when the intended use or fundamental scientific technology is changed for an exempt device.

When a new 510(k) is needed, consider the alternative means of submitting a 510(k) under the New 510(k) Paradigm. Refer to the New 510(k) Paradigm guidance "A New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", (www.fda.gov/cdrh/ode/parad510.html) for more information on the special 510(k) process. For instance, a Special 510(k) may be accepted for modification(s) to a manufacturer's own legally marketed medical washer-disinfector, provided the intended use of the device is not changed and there are no significant technological changes. The manufacturer should consider the extent of the intended change and evaluate whether the modification is significant in accordance with CDRH guidance on changes to 510(k)s entitled: "Deciding When to Submit a 510(k)

for a Change to an Existing Device," (www.fda.gov/cdrh/ode/510kmod.pdf). The manufacturer is responsible for determining whether a change to a device is significant and needs a new 510(k). In any case, the change must be validated according to design control regulations.

Significant modifications to a legally marketed medical washer or medical washer-disinfector which may require a new 510(k) submission include, but are not limited to, the following examples:

1. a change in fundamental scientific technology, such as a change from a thermal disinfection process to a chemical disinfection process

2. a change in intended use, such as a change from washing to high level disinfection for a medical washer, or when the labeling is modified to include, for the first time, devices with features that are generally recognized as very difficult to clean or disinfect successfully, such as narrow lumened endoscopic devices or minimally invasive surgical instruments.

Note: Modifications to a device exempt from the 510(k) submission requirements must be validated according to design control regulations. If the modifications remove the device from an exempt status, a new 510(k) submission is required.

F. Reprocessing Endpoints for Medical Devices

Spaulding Classification and Disinfection Levels

Researchers have developed schemes for categorizing devices to help determine what degree of reprocessing is needed for a device before it is used on another patient. The FDA relies upon both the Spaulding classification (Spaulding 1971, 1972) and the Centers for Disease Control and Prevention recommendations (Favero, 1995) for the degree of reprocessing for a medical device. According to the Spaulding classification, a medical device is categorized into one of three classes based on patient contact during use: skin contact, mucosal contact, or invasive. The device categories that correspond to the three patient contact classes are noncritical, semicritical, and critical, respectively.

The desired reprocessing endpoint for a device depends on its Spaulding category. Cleaning is necessary for all three categories of devices to remove visible soil. A noncritical medical device may only require cleaning to make the device patient ready. In other cases, a noncritical medical device may require low or intermediate disinfection prior to patient use. A semicritical device should be sterilized before reuse, if feasible; however, high level disinfection is an acceptable final process when sterilization is not an option. Critical devices must be sterilized before reuse.

The Intended Use for Medical Washers and Medical Washer-Disinfectors

The intended use for a medical washer includes cleaning and drying of medical devices. The intended use for a medical washer-disinfector includes cleaning, decontamination or disinfection (low, intermediate, or high level), and drying of medical devices. The data for a 510(k) submission and for design control must document that the device achieves its intended use. In addition, data in the 510(k) submission must demonstrate equivalent safety and performance to a legally marketed predicate device with the same intended use.

G. Document Availability

The following relevant FDA documents are available from the Division of Small Manufacturers Assistance (DSMA) [(800) 638-2041 or (301) 443-6597] or on the CDRH website under guidance documents:

1. Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, issued 5/29/98

2. Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectant, issued 1/3/2000

3. Clarification on Cleaning Agents and General Purpose Disinfectants that require a 510(k) Submission, issued May 3, 1995

II. Content and Organization of Information to be Provided in a 510(k) Submission for Washer-Disinfectors Intended to Clean and Provide High Level Disinfection of Medical Devices

A. Cover Letter

The 510(k) submission should include a cover letter providing the following information described in 21 CFR §807.87 (Information required in a 510(k) submission):

1. Trade or proprietary name of the device

2. Common or usual name of the device: medical washer-disinfector

3. Intended use of the device: high level disinfection of medical devices

4. FDA review panel code: 80

5. FDA review product code:

thermal disinfection, pasteurization systems: LDS

liquid chemical disinfection systems: MEC

6. Establishment registration number, if applicable, of the sponsor, owner, or operator submitting the premarket notification

7. Class in which the device has been placed under section 513 of the act, and the appropriate panel, if known: Class II (proposed)

8. A statement explaining the purpose of the submission and type of 510(k) (e.g., special 510(k), abbreviated 510(k), or traditional 510(k))

   Refer to the 510(k) Paradigm guidance on the FDA website for additional information on different types of 510(k) submissions (www.fda.gov/cdrh/ode/parad510.html)

9. The name, address and telephone number of individual(s) in the U.S.A. that may be contacted regarding the submission

10. The name and address of each facility that will be used for manufacturing the washer-disinfector

B. Table of Contents

The 510(k) submission should include a table of contents noting sections, titles, and pages.

C. Administrative Information

1. Under the Safe Medical Device Amendments of 1990, the 510(k) must include either: (1) a summary of the safety and effectiveness information in the 510(k) upon which an equivalence determination could be based [510(k) summary]; or (2) a statement that safety and effectiveness information will be made available to interested persons upon request [510(k) statement]. In addition, persons who submit a 510(k) must certify that to the best of their knowledge, all information is truthful and accurate and that no material fact has been omitted (Truthful and Accurate Statement).

   a. Safety and effectiveness information refers to information in the 510(k), including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be either descriptive information or performance or clinical testing information about the new and predicate device(s). A summary shall be

in a separate section and be clearly labeled as the 510(k) summary of safety and effectiveness.

b. The regulations for the 510(k) Summary, the 510(k) Statement, and the Truthful and Accurate Statement are in 21 CFR 807.92, 807.93, and 807.87(k), respectively. FDA cannot complete the review of the 510(k) submission without the 510(k) summary or statement and the Truthful and Accurate Statement.

2. The 510(k) must include an Indications for Use Statement. The FDA website contains a recommended format for the Indications for Use Statement (www.fda.gov/cdrh/devadvice).

Additional information about the 510(k) administrative requirements can be obtained from the FDA Division of Small Manufacturers Assistance (www.fda.gov/cdrh/dsma/dsmamain.html).

D. Comparison to a Predicate Device

The 510(k) submission should include a detailed summary table comparing the washer-disinfector to a predicate device. More than one predicate device can be listed. Ideally, the new device should be similar to the predicate(s) with regard to intended use and critical design aspects to optimize the chance for a finding of equivalence. The following are examples of important comparisons:

1. intended use, listing both similarities and differences of the new device and the predicate;

2. operational principles; and

3. critical design features, process monitors, and process parameters.

E. Authorization for Data Access

If the 510(k) submission includes references to data and/or information on file with another agency or in a device master file, FDA recommends that the person submitting the 510(k) submission include a letter from the file's owner authorizing FDA's use of the file.

F. Labels and Labeling

1. Proposed Labels and Labeling: The 510(k) submission must contain proposed labels, labeling, and other promotional materials sufficient to describe the device, its intended use, and the directions for use [21 CFR 807.87(e)]. Labels

include the information affixed directly to the device and its packaging. Labeling also includes the user's manual, service manual, and any other information that accompanies the device. The service manual does not have to be included in a 510(k) submission.

2. Labeling Requirements: Labeling must meet the requirements of 21 CFR Part 801. FDA's premarket review will concentrate on the following:

   a. Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use

   b. Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions

3. User's Manual: The user's manual should contain at a minimum the following information, if applicable:

   a. type and model designation

   b. name and address of the manufacturer and/or distributor

   c. the intended use of the medical washer-disinfector

   d. instructions for the user on how to select devices that are compatible with the medical washer-disinfector

   e. limitations of use, that is, any special characteristics of certain types of medical devices or their accessories which require special handling or which may not be adequately processed by the medical washer-disinfector

   f. electrical safety instructions

   g. installation instructions and input requirements

   h. detailed operating or use instructions; the instructions should identify when various default or optional modes are applicable

   i. pre and post process instructions to compliment the cleaning and disinfection instructions provided by the device manufacturer

   j. a list of the generic types of accessory solutions, such as detergent(s), enzymatic cleaner(s), lubricant(s), and germicide(s), which are compatible with the medical washer-disinfector

k. general instructions on the use of the accessory solutions with the medical washer-disinfector which compliment the labeling for the accessory solutions

l. additional instructions, if necessary, on the monitoring of a liquid chemical germicide beyond that provided by the germicide manufacturer for medical washer-disinfectors with disinfection cycles that use a liquid chemical germicide

m. identification of the dilution factor of the germicide per machine cycle, if applicable, for medical washer-disinfectors that use a liquid chemical germicide for the disinfection cycle

n. error or fault indications, their causes, and user response

o. interpretation and use of indicator gauges

p. instructions for disinfecting the machine itself and the frequency that the self-disinfection cycle should be run, unless data are included in the 510(k) submission showing that such a process is not needed

q. any applicable warnings, hazards, and precautions

r. other relevant information regarding the use of the medical washer-disinfector, such as input water quality, temperature, water pressure, air pressure, and flow rates

s. maintenance schedules and identification of the responsible parties

t. contact for assistance if the user has questions

G. Voluntary Consensus Standards and Other Standards

A manufacturer may utilize a standard in the 510(k) submission in design validation and verification tests. The standard may be a voluntary consensus standard that is published by a standards development organization, such as, AAMI or ISO, a regulatory standard, an internal standard of the manufacturer, or another type of standard.

FDA has recognized many standards and published these standards on the CDRH website:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA recognition of a standard signifies that the standard addresses critical design and testing aspects and that FDA is familiar with the standard.

The 510(k) submission should identify the standard and discuss how it was used. The manufacturer may choose to declare conformity to a recognized standard or to submit a certification as noted in the CDRH document on the use of standards "Guidance on the Recognition and Use of Consensus Standards", issued 2/19/98. A certification should include the same type of information contained in a declaration of conformity to a recognized standard. The document "A New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" also contains information on certification of conformance to voluntary standards. Manufacturers are obliged to meet a standard to which they declare or certify and must maintain documentation of testing showing that the device meets the standard.

H. Description of the Medical Washer-Disinfector

1. Overview

   a. Provide an overview of the medical washer-disinfector. This should include the intended use and the Indication for Use Statement. This description can include labeled drawings, photographs, and brochures that show the interior dimensions and locations of the major components.

   b. Provide labeled diagrams showing how each cycle operates, including critical components and fluid paths. Providing this information in the form of colored diagrams has proven to be an efficient and effective form of documentation.

   c. Illustrate in labeled diagrams the fluid pathway(s) of the medical washer-disinfector through all racks and other accessories. As above, color enhancements are useful means of documentation.

   d. Describe all accessory racks, trays, and attachments provided for use with the medical washer-disinfector.

   e. Provide the formulations for the concentrates and the in-use dilutions for all accessory solutions, such as detergents, lubricants, enzyme detergents, or germicides, whose use is critical to the performance or dedicated to the specific device. Include efficacy testing as recommended in the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants", issued 1/3/2000 for any proprietary liquid chemical sterilant/high level disinfectant which is not FDA cleared.

2. Process Monitors

Provide a complete description and location of the components used to monitor the process. Include information on specifications of the instruments and sensors (accuracy, precision, range, specificity, and sensitivity).

3. Process Parameters

a. Describe the process parameters and their tolerances for each process variable and compare them to the predicate device(s). The process variables may include time, temperature, water quality, water pressure, fluid flow rates, pre-processing conditions, post-processing conditions, etc. Identify the factors that affect the effectiveness of the processes and state how they are controlled.

b. Provide the rationale for each process parameter and tolerance.

c. Describe all fault conditions related to each of the process parameters, including under what conditions a fault is detected and how the medical washer-disinfector will respond. Provide the rationale for each.

I. Performance Data

1. Introduction

In general, medical washer-disinfectors intended to reprocess medical devices work in combination with detergents, enzyme cleaners, lubricants, and with some medical washer-disinfectors, liquid chemical germicides, to eliminate contamination. The electromechanical aspects of a medical washer-disinfector can be evaluated on the basis of engineering specifications and tests. However, since the device is designed to work in combination with other products as a system to achieve its intended use, the FDA believes that test data should indicate the ability of the medical washer-disinfector to clean and disinfect medical devices prior to their use on patients or their exposure to a terminal process, such as sterilization.

2. Process Parameter Physical Tests

a. Test data should demonstrate that the machine achieves and maintains the specified physical parameters within specified tolerances for the critical process variables, such as time, temperature, water pressure,

fluid flow rates, concentration and delivery of accessory solutions, etc., for each of the cycles under the load conditions specified in labeling. Test data should show that the process monitors accurately reflect the chamber conditions. Testing should be done under empty chamber and full chamber conditions. The full chamber load should include representative types of devices identified in the labeling as being compatible with the medical washer-disinfector and the accessory racks. The empty and full chamber testing should be repeated a minimum of three runs to demonstrate repeatability. The manufacturer should include a summary of these tests in the 510(k) submission.

b. For thermal disinfection processes, data should show that the instruments in the loads reach and maintain the disinfection setpoint temperature for the specified contact time. For chemical disinfection processes, data should show that the disinfectant reaches and maintains the specified contact conditions.

3. Simulated-use Tests

a. Overview

Microbiological and chemical test data should separately demonstrate that the washer-disinfector delivers the cleaning and disinfection steps for the contact conditions necessary to achieve machine's intended use when operated in accordance with these directions.

Simulated-use testing should evaluate the performance of the medical washer-disinfector under "worst case conditions." FDA defines "worst case conditions" as testing at the minimum parameters for the process variables in each cycle. For example, worst case conditions could be testing done at the minimum temperature, pressure, flow rates, contact times, fluid concentration, and just prior to any scheduled maintenance. In addition, the FDA recommends that the simulated-use testing include medical devices which have been previously processed in order to evaluate realistic conditions.

b. Simulated-use test documentation should include the following:

(1) a rationale for selection of test devices (i.e., that the devices are a significant challenge in processing)

(2) the methods by which the devices are contaminated (inoculated) and treated prior to exposure to the processing steps, including validation of the methods

(3) the recovery method used to evaluate the devices after exposure to the processing steps, including data to show the ability of the recovery method to detect low numbers of injured organisms from the processed devices

(4) 3 replicate runs with devices, which represent the "worst case" challenge to the process

(5) separate evaluation of the effectiveness of each processing step (cleaning, disinfection, rinsing, etc.) under "worst case" conditions as recommended below

(6) the description of and data from concurrent controls run with each test

c. Cleaning Efficacy

The evaluation of the cleaning step should demonstrate the effectiveness of the cleaning step independently of any other step. The manufacturer should define the appropriate pass/fail criteria for cleaning, provide the scientific rationale for the pass/fail criteria, and show how these criteria relate to the clinical environment. The test criteria should evaluate the ability of the cleaning step to remove a defined organic challenge. The FDA recommends that current, relevant standards and professional practices be evaluated to help determine the challenge and pass/fail criteria for tests. FDA recommends that the challenge be a realistic representation of the type of soil to which devices are exposed during clinical use. The test data should demonstrate that the pass/fail criteria are consistently achieved for the devices identified in labeling as compatible with the medical washer-disinfector. Because the microbial log reduction method used to evaluate cleaning may not be directly related to a clinical cleaning endpoint, such as visibly clean, the FDA recommends that the manufacturer use both a visual and a quantitative method to assess cleaning efficacy. The FDA does not believe that the microbial log reduction method, by itself, is sufficient to document achievement of the pass/fail criteria for cleaning because it does not exclude the retention of visible soil or contaminates.

Note: Until there are standardized criteria and methods for testing the cleaning functions of medical washer-disinfectors, the manufacturer can compare the performance of its machine to the predicate to show equivalent cleaning efficacy.

d. Disinfection Efficacy

The evaluation of the disinfection step for the medical washer-disinfector should demonstrate the effectiveness of the disinfection step independent of the cleaning step. A cleaning step is primarily a mechanical process while disinfection is a microbicidal process. The disinfection step documentation should show that a lethal agent is delivered to the medical devices under the conditions necessary to achieve the desired level of disinfection. This can be demonstrated by the achieving the lethality endpoint for the desired level of disinfection. The FDA will also consider other methods demonstrating that the critical parameters for the disinfection step are achieved. If disinfection is achieved by means of a thermal process, the manufacturer should test at the minimum contact conditions of time and temperature.

If disinfection is achieved through use of a liquid chemical sterilant/high level disinfectant, the manufacturer should test the disinfecting step using a germicide that is acceptable for use in the medical washer-disinfector per the germicide labeling. Germicide effectiveness is affected by dilution and degradation in a machine so the tests and documentation must assess these adverse phenomena to determine if the germicide can be used according to its labeling or whether other instructions are needed. Documentation of the efficacy of liquid chemical sterilants/high level disinfectants that do not have FDA clearance will need to be supplied. For additional information see the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants", issues 1/3/2000.

The evaluation of the disinfection step should include the following:

(1) identificaton of devices that represent significant challenges to the disinfection step within the scope of the intended use

(2) use of appropriate test organisms, which are suspended in an organic challenge, for the desired level of disinfection

(3) placement of a quantified inoculumn in locations on the devices that represent the greatest challenge (the inoculated sites should be visibly dried prior to exposure to the disinfection step)

(4) The FDA's recommended endpoint for high level disinfection is as follows:

High level disinfection: 6-log reduction of a mixed suspension

of vegetative organisms, such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, and representatives of the Klebsiella-Enterobacter group and a 6-log reduction of an appropriate mycobacterium species. For thermal disinfection processes, FDA recommends the use of a thermophilic mycobacterium species. The degree of microbicidal kill is based upon the FDA guidance for liquid chemical sterilants/high level disinfectants and on equivalent performance of legally marketed washer-disinfectors.

Note: If the quantified challenge on the devices exposed to the disinfection step is 10^6 organisms per device, the FDA expects no survivors remaining on the device.

e. Rinsing Efficacy

The evaluation of rinsing efficacy should show that the rinse steps remove the residues of the cleaning and disinfection steps to levels that are not a hazard to the patient or the end-user or interfere with a terminal process, such as sterilization.

f. Self-Disinfection Efficacy

If a medical washer-disinfector has a self-disinfection cycle, tests should be conducted to demonstrate that the defined endpoint for the self-disinfection cycle is achieved. The test protocol for the self-disinfection cycle for a medical washer-disinfector should reflect the use conditions that the machine would experience in a hospital setting. For example, FDA recommends that testing be conducted after multiple cycles have been run in the machine for the period between recommended self-disinfection cycles. All areas, which could become colonized, such as tubing, connections, filters, etc., should be microbiologically evaluated before and after the self-disinfection cycle. Culture conditions appropriate for the recovery of water borne microorganisms should be used.

Tests should include positive and negative controls. Failures to achieve the desired outcome must be analyzed and reported. Assignment of the mode of failure must be justified, e.g., device related, procedure related, etc.

g. Other Testing

Testing should be conducted to demonstrate that defined endpoints for

other functions of medical washer-disinfectors not specifically discussed above are achieved.

4. In-use Testing

In-use testing data should demonstrate that the medical washer-disinfector achieves the claimed endpoints under actual use. Simulated-use tests alone may not sufficiently verify proper performance. With both types of tests, there is a greater likelihood that the design will be adequately validated. FDA recommends that the validation test document include the following:

a. A protocol with a description of the methods used to evaluate the processed devices. FDA recommends that the same methods that were validated for the simulated-use testing be used for the in-use testing. The devices, which represent the greatest challenge to the medical washer-disinfector processes, should be included in the in-use testing.

b. FDA recommends that the manufacturer evaluate appropriate control devices to determine the bioburden present before processing. FDA realizes that the bioburden on control samples may not be indicative of the bioburden on devices placed in the machines.

J. Toxicological Evaluation of Residues

1. Determination of Residues

Documentation should include an assessment of the level of any residues (e.g., detergents, lubricants, and germicides) remaining on the medical devices after processing in the medical washer-disinfector. The examination of chemicals need not be exhaustive, only indicative of common agents.

2. Hazard Evaluation of Residues

To ensure safe conditions of use of the medical device following processing, the manufacturer should document either that there are no detectable residues remaining on the device, or that the cycle removes the residues to a nontoxic level. The risk from the chemical residue can be determined by reviewing the available toxicity data of the particular residual chemical from animal toxicity studies sponsored by the manufacturer of the chemical, MSDS sheets, from the published literature, or by other means.

K. Software Documentation

Verification tests should include the validation of any software (or firmware). FDA recommends that the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued 5/29/98 be used to evaluate any software (or firmware). The guidance is available from DSMA. Unless otherwise directed by FDA, a medical washer-disinfector intended for terminal processing, such as high level disinfection, is considered to be in a "moderate" risk category as described in the software guidance document.

L. Electrical Safety Documentation

Verification tests should demonstrate that the device is electrically safe.

M. Electromagnetic Compatibility

Verification tests should demonstrate the device exhibits electromagnetic compatibility within its normally used environment.

III. Content of Information and Data to be Included in Design Control Records

This section of the special control guidance provides recommendations for the content of the design control records for those medical washers and medical washer disinfectors that are exempt from 510(k) requirements. It should also be noted that the information and data for design control records are parts of quality systems records, in accordance with quality system regulations. This information reiterates recommendations included in Section II of this guidance.

A. Labels and Labeling

1. Proposed Labels and Labeling: The design control documentation must contain proposed labels, labeling, and other promotional materials sufficient to describe the device, its intended use, and the directions for use [21 CFR 807.87(e)].

Labels include the information affixed directly to the device and its packaging. Labeling also includes the user's manual, service manual, and any other information that accompanies the device. The service manual does not have to be included in a 510(k) submission.

2. Labeling Requirements: Labeling must meet the requirements of 21 CFR Part 801. FDA's premarket review will concentrate on the following:

    a. Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use

    b. Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions

3. User's Manual: The user's manual should contain at a minimum the following information, if applicable:

    a. type and model designation

    b. name and address of the manufacturer and/or distributor

    c. the intended use of the medical washer or medical washer-disinfector

    d. instructions for the user on how to select devices that are compatible with the medical washer or medical washer-disinfector

    e. limitations of use, that is, any special characteristics of certain types of medical devices or their accessories which require special handling or which may not be adequately processed by the medical washer or medical washer-disinfector

    f. electrical safety instructions

    g. installation instructions and input requirements

    h. detailed operating or use instructions; the instructions should identify when various default or optional modes are applicable

    i. pre and post process instructions to compliment the cleaning and disinfection instructions provided by the device manufacturer

j. a list of the generic types of accessory solutions, such as detergent(s), enzymatic cleaner(s), lubricant(s), and germicide(s), which are compatible with the medical washer or medical washer-disinfector

k. general instructions on the use of the accessory solutions with the medical washer or medical washer-disinfector which compliment the labeling for the accessory solutions

l. additional instructions, if necessary, on the monitoring of a liquid chemical germicide beyond that provided by the germicide manufacturer for medical washer-disinfectors with disinfection cycles that use a liquid chemical germicide

m. identification of the dilution factor of the germicide per machine cycle, if applicable, for medical washer-disinfectors that use a liquid chemical germicide for the disinfection cycle

n. error or fault indications, their causes, and user response

o. interpretation and use of indicator gauges

p. instructions for disinfecting the machine itself and the frequency that the self-disinfection cycle should be run, unless data are included in the 510(k) submission or in the design control records showing that such a process is not needed

q. any applicable warnings, hazards, and precautions

r. other relevant information regarding the use of the medical washer or medical washer-disinfector, such as input water quality, temperature, water pressure, air pressure, and flow rates

s. schedules for maintenance and identification of the responsible parties

t. the contact for assistance if the user has questions

B. Voluntary Consensus Standards and Other Standards

A manufacturer may utilize a standard in the design control process as input for design purposes, in verification tests, and design validation. The standard may be a voluntary consensus standard that is published by a standards development organization, such as, AAMI or ISO, a regulatory standard, an internal standard of the manufacturer, or another type of standard.

FDA has recognized many standards and published these standards on the CDRH website:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA recognition of a standard signifies that the standard addresses critical design and testing aspects and that FDA is familiar with the standard.

The design control records should identify the standard and discuss how it was used. The manufacturer may choose to declare to a recognized standard or to submit a certification as noted in the CDRH document on the use of standards "Guidance on the Recognition and Use of Consensus Standards", issued 2/19/98. A certification should include the same type of information contained in a declaration to a recognized standard. The document "A New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" also contains information on certification of conformance to voluntary standards. Manufacturers are obliged to meet a standard to which they declare or certify and must maintain documentation of testing showing that the device meets the standard.

C. Description of the Medical Washer and Medical Washer-Disinfector

IMPORTANT NOTE: The description of the medical washer and medical washer-disinfector is primarily applicable to the 510(k) submission for a medical washer-disinfector intended for the cleaning and high level disinfection of medical devices. A manufacturer of a medical washer or medical washer-disinfector exempt from 510(k) requirements may also find it useful to include this type of documentation in its design control records for audit purposes.

1. Overview

    a. Provide an overview of the medical washer or medical washer-disinfector. This should include the intended use and the Indication for Use Statement. This description can include labeled drawings, photographs, and brochures that show the interior dimensions and locations of the major components.

    b. Provide labeled diagrams showing how each cycle operates, including critical components and fluid paths. Providing this information in the form of colored diagrams has proven to be an efficient and effective form of documentation.

    c. Illustrate in labeled diagrams the fluid pathway(s) of the medical washer or medical washer-disinfector through all racks and other accessories. As above, color enhancements are useful means of documentation.

d. Describe all accessory racks, trays, and attachments provided for use with the medical washer or medical washer-disinfector.

e. Provide the formulation for the concentrate and the in-use dilution for all accessory solutions, such as detergents, lubricants, enzyme detergents, or germicides, whose use is critical to the performance or dedicated to the specific device. Include efficacy testing as recommended in the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants", issued 1/3/2000 for any proprietary liquid chemical sterilant/high level disinfectant which is not FDA cleared.

2. Process Monitors

Provide a complete description and location of the components used to monitor the process. Include information on specifications of the instruments and sensors (accuracy, precision, range, specificity, and sensitivity).

3. Process Parameters

a. Describe the process parameters and their tolerances for each process variable and compare them to the predicate device(s). The process variables may include time, temperature, water quality, water pressure, fluid flow rates, pre-processing conditions, post-processing conditions, etc. Identify the factors that affect the effectiveness of the processes and state how they are controlled.

b. Provide the rationale for each process parameter and tolerance.

c. Describe all fault conditions related to each of the process parameters, including under what conditions a fault is detected and how the medical washer or medical washer-disinfector will respond. Provide the rationale for each.

D. Performance Data

1. Introduction

In general, medical washers and medical washer-disinfectors intended to reprocess medical devices work in combination with detergents, enzyme cleaners, lubricants, and with some medical washer-disinfectors, liquid chemical germicides, to eliminate contamination. The electromechanical aspects of a medical washer or medical washer-disinfector can be evaluated on the basis of engineering specifications and tests. However, since the device is designed to

work in combination with other products as a system to achieve its intended use, the FDA believes that test data should indicate the ability of the medical washer to produce a clean device, and for the medical washer-disinfector to clean and disinfect medical devices prior to their use on patients or their exposure to a terminal process, such as sterilization.

2. Process Parameter Physical Tests

   a. Test data should demonstrate that the machine achieves and maintains the specified physical parameters within specified tolerances for the critical process variables, such as time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions, etc., for each of the cycles under the load conditions specified in labeling. Test data should show that the process monitors accurately reflect the chamber conditions. Testing should be done under empty chamber and full chamber conditions. The full chamber load should include representative types of devices identified in the labeling as being compatible with the medical washer or medical washer-disinfector and the accessory racks. The empty and full chamber testing should be repeated a minimum of three runs to demonstrate repeatability. The manufacturer should include a summary of these tests in the design control records.

   b. For thermal disinfection processes, data should show that the instruments in the loads reach and maintain the disinfection setpoint temperature for the specified contact time. For chemical disinfection processes, data should show that the disinfectant reaches and maintains the specified contact conditions.

3. Simulated-use Tests

   a. Overview

      Microbiological and chemical test data should demonstrate that the medical washer delivers a cleaning step for the contact conditions necessary to achieve the machine's intended use when operated in accordance with the directions for use. The microbiological and chemical test data should separately demonstrate that the washer-disinfector delivers the cleaning and disinfection steps for the contact conditions necessary to achieve machine's intended use when operated in accordance with these directions.

      Simulated-use testing should evaluate the performance of the medical

washer or medical washer-disinfector under "worst case conditions." FDA defines "worst case conditions" as testing at the minimum parameters for the process variables in each cycle. For example, worst case conditions could be testing done at the minimum temperature, pressure, flow rates, contact times, fluid concentration, and just prior to any scheduled maintenance. In addition, the FDA recommends that the simulated-use testing include medical devices which have been previously processed in order to evaluate realistic conditions.

The degree of testing required for the medical washer or medical washer-disinfector is dependent upon the intended use of the device. If the intended use of the device is only as a medical washer, then the manufacturer only needs to evaluate the cleaning step for each cycle. If the intended use of the device includes both cleaning and disinfection, then the manufacturer needs to evaluate both the cleaning and disinfection steps for each cycle.

b. Simulated-use test documentation should include the following:

(1) a rationale for selection of test devices (i.e., that the devices are a significant challenge in processing)

(2) the methods by which the devices were contaminated (inoculated) and treated prior to exposure to the processing steps, including validation of the methods

(3) the recovery method used to evaluate the devices after exposure to the processing steps, including data to show the ability of the recovery method to detect low numbers of any injured organisms remaining on the test devices

(4) 3 replicate runs with devices, which represent the "worst case" challenge to the process

(5) separate evaluation of the effectiveness of each processing step (cleaning, disinfection, rinsing, etc.) under "worst case" conditions as recommended below

(6) the description of and data from concurrent controls run with each test

c. Cleaning Efficacy

The evaluation of the cleaning step should demonstrate the effectiveness of the cleaning step independently of any other step. The manufacturer should define the appropriate pass/fail criteria for cleaning, provide the scientific rationale for the pass/fail criteria, and show how these criteria relate to the clinical environment. The test criteria should evaluate the ability of the cleaning step to remove a defined organic challenge. The FDA recommends that current, relevant standards and professional practices be evaluated to help determine the challenge and pass/fail criteria for tests. FDA recommends that the challenge be a realistic representation of the type of soil to which devices are exposed during clinical use. The test data should demonstrate that the pass/fail criteria are consistently achieved for the medical devices identified in labeling as compatible with the medical washer or medical washer-disinfector. Because the microbial log reduction method used to evaluate cleaning may not be directly related to a clinical cleaning endpoint, such as visibly clean, the FDA recommends that the manufacturer use both a visual and a quantitative method to assess cleaning efficacy. The FDA does not believe that the microbial log reduction method, by itself, is sufficient to document achievement of the pass/fail criteria for cleaning because it does not exclude the retention of visible soil or contaminates.

Note: Until there are standardized criteria and methods for testing the cleaning functions of medical washers and medical washer-disinfectors, the manufacturer can compare the performance of its device to the predicate device to show equivalent cleaning efficacy.

d. Disinfection Efficacy

The evaluation of the disinfection step for the medical washer-disinfector should demonstrate the effectiveness of the disinfection step independently of the cleaning step. A cleaning step is primarily a mechanical process while disinfection is a microbicidal process. The disinfection step documentation should show that a lethal agent is delivered to the devices under the conditions necessary to achieve the desired level of disinfection. This can be demonstrated by achieving the lethality endpoint for the desired level of disinfection. The FDA will also consider other methods demonstrating that the critical parameters for the disinfection step are achieved. If disinfection is achieved by means of a thermal process, the manufacturer should test at the minimum contact conditions of time and temperature.

If disinfection is achieved through use of a liquid chemical sterilant/high level disinfectant, the manufacturer should test the disinfecting step using a germicide that is acceptable for use in the medical washer-disinfector per the germicide labeling. Germicide effectiveness is affected by dilution and degradation in a machine so the tests and documentation must assess these adverse phenomena to determine if the germicide can be used according to its labeling or whether other instructions are needed. Documentation of the efficacy of liquid chemical sterilants/high level disinfectants that do not have FDA clearance will need to be supplied. For additional information see the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants," issued 1/3/2000.

The evaluation of the disinfection step should include the following:

(1) identification of devices that represent significant challenges to the disinfection step within the scope of the intended use

(2) use of appropriate test organisms, which are suspended in an organic challenge, for the desired level of disinfection

(3) placement of a quantified inoculumn in locations on the devices that represent the greatest challenge (the inoculated sites should be visibly dried prior to exposure to the disinfection step)

(4) The FDA's recommended endpoints for the different disinfection levels are as follows:

Low level disinfection: a 6-log reduction of a mixed suspension of typical vegetative organisms, such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, and representatives of the Klebsiella-Enterobacter group

Intermediate level disinfection: the 6-log reduction of the mixed suspension of vegetative organisms and a 3-log reduction of an appropriate mycobacterium species. For thermal disinfection processes, FDA recommends the use of a thermophilic mycobacterium species.

Note: For a low level or intermediate level thermal disinfection step closed ampoules containing the test suspensions suspended in an organic soil may be substituted for direct inoculation of the test devices. The ampoules should be placed in locations in the chamber and racks identified as the most difficult to disinfect.

e. Rinsing Efficacy

The evaluation of rinsing efficacy should show that the rinse steps remove the residues of the cleaning and disinfection steps to levels that are not a hazard to the patient or the end-user or interfere with a terminal process, such as sterilization.

f. Self-Disinfection Efficacy

If a medical washer or medical washer-disinfector has a self-disinfection cycle, tests should be conducted to demonstrate that the defined endpoints for the self-disinfection cycle are achieved. The test protocol for the self-disinfection cycle for a medical washer or medical washer-disinfector should reflect the use conditions that the device would experience in a hospital setting. For example, FDA recommends that testing be conducted after multiple cycles have been run in the machine for the period between recommended self-disinfection cycles. All areas, which could become colonized, such as tubing, connections, filters, etc., should be microbiologically evaluated before and after the self-disinfection cycle. Culture methods appropriate for the recovery of water borne microorganisms should be used.

Tests should include positive and negative controls. Failures to achieve the desired outcome must be analyzed and reported. Assignment of the mode of failure must be justified, e.g., device related, procedure related, etc.

g. Other Testing

Testing should be conducted to demonstrate that defined endpoints for other functions of medical washers and medical washer-disinfectors not specifically discussed above are achieved.

E. Toxicological Evaluation of Residues

1. Determination of Residues

   Documentation should include an assessment of the level of any residues (e.g., detergents, lubricants, and germicides) remaining on the medical devices after processing in the medical washer or medical washer-disinfector. The examination of chemicals need not be exhaustive, only indicative of common agents.

2. Hazard Evaluation of Residues

   To ensure safe conditions of use of the medical device following processing, the manufacturer should document either that there are no detectable residues remaining on the device, or that the process cycle removes the residues to a nontoxic level. The risk from the chemical residue can be determined by reviewing the available toxicity data of the particular residual chemical from animal toxicity studies sponsored by the manufacturer of the chemical, MSDS sheets, from the published literature, or by other means.

F. Software Documentation

Verification tests should include the validation of any software (or firmware). FDA recommends that the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued 5/29/98 be used to evaluate any software (or firmware). The guidance is available from DSMA. Medical washers and medical washer-disinfectors intended for the cleaning and either low or intermediate disinfection of medical devices are in a "minor" risk category.

G. Electrical Safety Documentation

Verification tests should demonstrate that the device is electrically safe.

H. Electromagnetic Compatibility

Verification tests should demonstrate the device exhibits electromagnetic compatibility within its normally used environment.

IV. Comments

General questions regarding the submission of 510(k) submission should be directed to DSMA at (800) 638-2041.

Questions or comments regarding this guidance should be directed to the following address:

FDA

Division of Dental, Infection Control and General Hospital Devices
Infection Control Devices Branch (HFZ-480)
9200 Corporate Blvd.
Rockville, MD 20850-4308

Reviewer Checklist for Medical Washers and Medical Washer-Disinfectors

510(k) #:_____ Sponsor:_____

Date:_____ Reviewer:_____

#	Y/N	Element
1.		Cover Letter
	____	proprietary name
	____	common or usual name
	____	classification name
	____	establishment registration number
	____	procode(s)
	____	purpose of the submission
	____	identification of the predicate devices
	____	previous files referenced
	____	contact person
2.		Labeling
	____	proposed labels and labeling
	____	labeling requirements
	____	user's manual
3.	____	Standards, Practices, Technical Reports
4.		Description of the Washer and Washer-disinfector
	____	overview of the washer and washer-disinfector
	____	Intended Use/Indications for Use(s)
	____	design, construction, components, accessories
	____	process monitors
	____	process parameters/development
5.	____	Descriptive Comparison to a Predicate

6.		Performance Data
	____	physical tests
	____	simulated-use tests
	____	in-use tests
	____	other
7.		Toxicological Evaluation of Residues
	____	residue evaluation
	____	hazard evaluation
8.	____	Software Documentation
9.	____	510(k) summary or statement
10.	____	Truthful and Accurate Statement

References for the Medical Washer and Medical Washer-Disinfector 510(k) Guidance

1. Association for Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices: Volumes 1 and 2: Sterilization, 1995 Edition.
2. Block SS. Definition of terms. In: Disinfection, sterilization and preservation. Fourth ed. Philadelphia: Lea and Febiger, 1991:18-25.
3. Favero, MS. Chemical germicides in the health care field: The perspective from the Centers for Disease Control and Prevention. In: Rutala WA (Ed.) Chemical Germicides in Health Care International Symposium, May 1994. Washington DC: Association for Professionals In Infection Control and Epidemiology, Inc., and Morin Heights, P.Q., Canada: Polyscience Publications, Inc. 1995; pp. 33-42.
4. Labeling Reusable Medical Devices for Reprocessing In Health Care Facilities: FDA Reviewer Guidance, April 1, 1996. (http://www.fda.gov/cdrh/ode/198.pdf)
5. Garner JS and Favero MS. CDC guidelines for handwashing and hospital environmental control, 1985. Infect. Control 1986; 7:231-235.
6. ODE Blue Book Memorandum #K97-1 January 10, 1997. Deciding when to submit a 510(k) for a change to an existing device.
7. Rutala WA. Guideline for selection and use of disinfectants. Am. J. Infect. Control 1990 18:99-117.
8. Spaulding EH. Chemical disinfection and antisepsis in the hospital. J. Hosp. Res. 1972; 9:5-31.
9. Spaulding EH. The role of chemical disinfection in the prevention of nosocomial infections. In: PS Brachman and TC Eickof (ed.), Proceedings of International Conference on Nosocomial Infections, 1970. American Hospital Association, Chicago. 1971:254-274.

Attachment 1

Example of a Comparison Table between the New Device and the Predicate Device

Feature	New Device	Predicate
Labeling		
Intended Use		
Operational Principles		
Design, construction, components		
Process monitors: recorders, gauges, printouts, etc.		
Process parameters: time temperature, input water quality, pressure, etc.		
Software/firmware controls		
Performance Claims: cleaning and disinfection endpoints		
Accessories: germicide, detergents, enzyme cleaners, etc.		
Racks, trays, adapters, etc.		

This table illustrates the types of comparisons that should be made, not necessarily the amount of information. It is not all inclusive.