

Guidance for Industry and/or for FDA  
Reviewers/Staff and/or Compliance

**Guidance on the Content and  
Format of Premarket Notification  
510(k) Submissions of Washers and  
Washer-Disinfectors**

*Draft Guidance – Not for Implementation*

**This guidance document is being distributed for comment purposes only.**

**Draft released for comment on [release date as stated in FR Notice]**



**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**

98 D-0729

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# **Preface**

## **Public Comment:**

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this draft document should be submitted to Docket No. assigned to that notice, 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.

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This 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).

FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a washer or washer-disinfector intended to process reusable medical devices must submit to FDA, and have cleared, a premarket notification [510(k)] submission prior to its introduction into interstate commerce. Regulations governing the general content and format of 510(k) submissions are codified under 21 Code of Federal Regulations, Part 807. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in guidance documents available from the CDRH Division of Small Manufacturers Assistance (DSMA). The intent of this guidance document is to provide 510(k) applicants specific additional directions regarding information and data which should be submitted to FDA in a 510(k) submission for a washer or washer-disinfector.

A safe and effective system to decontaminate or disinfect reusable medical devices intended for patient use is important in preventing nosocomial infections. FDA has considered two important public health implications in the regulation of washers and washer-disinfectors intended for use in processing reusable medical devices: (1) when a washer-disinfector is used as the terminal process and (2) the impact on the effectiveness of the terminal sterilization process when a washer or washer-disinfector is used during an intermediate cleaning step. FDA recognizes the interdependency of cleaning and the effectiveness of a terminal process. Thus, comprehensive and scientifically sound criteria for the evaluation of washers and washer-disinfectors are essential to ensure that these devices are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, the agency's 510(k) submission criteria for washers and washer-disinfectors to facilitate the assembly of necessary data, to maintain consistency of review, and to provide a more efficient regulatory process.

The document expresses FDA's recommendations as of the date noted on the cover page. The document is not static but will be periodically revised to keep it current with state of the art developments in this area. Comments on the document are welcome and should be sent to the address noted on the preceding page.

**TABLE OF CONTENTS**

I.	Introduction		
	A.	Scope	1
	B.	Purpose	1
	C.	Definitions	2
	D.	Device Modifications that Require a New 510(k) Submission	4
	E.	Principles Regarding Presentation of Data	5
	F.	Document Availability	7
II.	Content and Organization of Information in a 510(k)		
	A.	Cover Letter	8
	B.	Table of Contents	9
	C.	Information Required by the Safe Medical Devices Act of 1990	9
	D.	Comparison to the Predicate	9
	E.	Other Data and Information	10
	F.	Label and Labeling	10
		1. Proposed Label and Labeling	
		2. Labeling Requirements	
		3. User's Manual	
		4. Service Manual	
	G.	Standards, Practices, Technical Reports	12
	H.	Description of the Washer and Washer-Disinfector	13
		1. Overview	
		2. Intended Use	
		3. Design, Construction, Components, & Accessories	
		4. Process Monitors	
		5. Process Parameters/Development	

*Draft - Not for Implementation*

I.	Performance Data	14
	1. Process Parameter Tests	
	2. Simulated-use Tests	
	3. In-use Tests	
J.	Toxicological Evaluation of Residues	18
	1. Introduction	
	2. Hazard Evaluation	
K.	Software Documentation	18
L.	Electrical Safety Requirements	19
M.	Comments	19
N.	Reviewer's Checklist	20
	References	22
	Attachment 1, Comparison Table	23

**Guidance on Premarket Notification [510(k)] for**

**Washers and Washer-Disinfectors Intended to Process Reusable Medical Devices**

I. Introduction

A. Scope

This document provides guidance for the 510(k) review of washers and washer-disinfectors intended to process reusable medical devices. The types of devices within this generic class are those washers and washer-disinfectors which are electromechanical and microprocessor controlled. The reusable medical devices, which are processed in these washers and washer-disinfectors may be subjected to an additional processing step such as a terminal sterilization process or high-level disinfection in accordance with recognized standards of practice. In addition, the processing in the washer may be the terminal processing step for the reusable medical device. Decontamination or disinfection may be achieved by either a thermal disinfection cycle or by the use of a FDA cleared sterilant or EPA registered disinfectant depending upon the claimed level of disinfection, i.e. high level disinfection or decontamination.

Exclusions

This document does not address manual cleaning accessories, such as brushes, buckets, etc.

B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in the organization and preparation of premarket notifications for washers and washer-disinfectors intended to process reusable medical devices;
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 premarket notifications.

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 (or Precleaning): The removal, usually with detergent and water, of adherent visible soil (blood, protein substances and other debris) from the surfaces, crevices, serration, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination. (AAMI, 1995).
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).
4. Disinfectant: A chemical 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, since 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, 1970, 1972).

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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 the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. The objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised (21 CFR §801.4).
10. Indications for Use: An indication for use is “a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended” (Blue Book Memorandum K97-1). The indications include all the labeled patient uses of the device, for example:
  - a. the condition(s) or disease(s) to be screened, monitored, treated, or diagnosed,
  - b. prescription versus over-the-counter use,
  - c. part of the body or type of tissue applied to or interacted with,
  - d. frequency of use,
  - e. physiological purpose (e.g. removes water from blood, transports blood, etc.), or
  - f. patient population.
11. Medical Device (as defined by the 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 Pharmacopeia, 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.
12. Process Residue: The substance remaining on a medical device after exposure to a decontamination, disinfection, or terminal sterilization process.

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13. 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.
14. Sterilant: An agent which destroys all viable forms of microbial life.
15. 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 disinfection), or a portion of a device.
16. Validation: confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled (Sec. 820.3 of the FDA Quality System Regulation 1990).

D. Device Modifications that Require a New 510(k) Submission

21 CFR 807.81 specifies that a premarket notification is required when modifications are made that could significantly affect safety or effectiveness of the device. Significant modifications to a legally marketed washer or washer-disinfector which would require a new premarket notification include, but are not limited to, the following examples:

1. a change in the processing cycles, such as the addition of a new cycle; a change from a thermal disinfection process to a chemical disinfection process, or a change in the cycle parameters, such as changes in the contact conditions of time and temperature for thermal processes or changes in the recommended minimum concentration and contact conditions for disinfection cycles based on the use of a liquid chemical germicide.
2. a change in the indication for use, such as a change in the lethality claims for the washer or washer-disinfector from decontamination to high level disinfection or the addition of categories of devices with restricted design features which require the use of specially designed racks or trays.

The following documents also provide additional information on when a device modification requires a new 510(k) submission and on the types of premarket notifications that are available to the manufacturer:

“Deciding when to submit a 510(k) for a change to an existing device,” Blue Book Memorandum K97-1, January 10, 1997

“A New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications”, issued 6/18/97

E. Principles Regarding Presentation of Data

1. Editorial Considerations: The 510(k) should be carefully edited, as well as scientifically reviewed before it is submitted to FDA. It should be proofread to assure that all pages/sections are included and are properly indicated, consecutive, distinctly copied, and legible.
2. Abbreviations: Standard abbreviations acceptable to a peer reviewed journal should be used wherever possible. All other 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, those submitting applications 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 equivalence.

Applicants should keep data used for the 510(k) submission on file in a controlled and well organized format. This will allow the applicant to supply FDA with additional information or analysis if required. Errors in data that are identified by the applicant after submission to FDA should be brought to FDA's attention immediately.

4. Tables and Graphs: Well-constructed tables are fundamental to the reporting and evaluation of data. All tables should be clearly identified and captioned with symbols keyed to a footnote or accessible reference page which 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. All referenced reports and data should be summarized including an explanation of how it relates to the current submission. Reference citations should be complete (e.g., title, author, journal, volume, year).
6. Protocols and Data Analysis: Test reports should include the protocol (objectives, precise description of materials, experimental methods, controls, observations, statistical methods and analyses, conclusions and

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comments.) Additional specific directions on protocols are included in the sections that follow.

7. Reference to Submitted Data: The applicant may reference any information previously submitted to FDA in support of the 510(k). If the applicant did not submit the referenced data, the applicant should either provide the referenced 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. The 510(k) should include a response to all elements in Part II below or include an explanation for why the data or information have not been supplied, or why alternative information is justified. Original 510(k)s that are grossly incomplete following a cursory review will be immediately deleted with notification to the applicant.

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

c. Under Section 807.87(h), the 510(k) may be amended to include any 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. Notification of needed information may be made by telephone and/or in writing. Telephone contact will typically be used to clarify minor deficiencies. Once the applicant is notified of the deficiencies, the 510(k) will be placed on hold. The applicant may elect to do one of the following:

1. provide the requested information;
2. formally withdraw the 510(k) submission;
3. allow the submission to be withdrawn administratively;

Administrative withdrawal will occur automatically after 30 days if a response to the request for information is not received by FDA. Extensions of the 30-day response period may be requested by submitting a written request to the Document Mail Center for an extension, clearly

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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 FDA believes a firm cannot respond completely within 30 days, the 510(k) will be immediately deleted with notification to the applicant.

Responses to FDA letters or telephone calls requesting additional information must 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 FDA may place the file on hold again after the applicant 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 applicant should respond fully to the request for information

4. The FDA strongly recommends that nonclinical laboratory studies submitted as part of a 510(k) submission be conducted according to GLP regulations, 21 CFR Part 58. Compliance with GLP regulations will ensure the quality and integrity of the submitted data.

F. Document Availability

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

CDRH Guidance Document for Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices, issued 4/30/98

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

Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants, issued 12/18/97

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

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Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Healthcare Facilities, issued August, 1993

II. Content and Organization of Information in a 510(k)

A. Cover Letter

The submission shall have a cover letter providing the following information described in 21 CFR §807.87 (Information required in a premarket notification submission):

1. Trade or proprietary name of the device
2. Common or usual name of the device: washer, washer-disinfector for reusable medical devices
3. The FDA product code:  
  
hot water, pasteurization systems: LDS  
liquid chemical disinfection systems: MEC
4. The FDA review panel code: 80
5. The establishment registration number, if applicable, or the sponsor, owner or operator submitting the premarket notification.
6. Class in which the device has been placed under section 513 of the act, and the appropriate panel, if known: unclassified.
7. A statement explaining the purpose of the submission (e.g., new device, significant modification of a device previously found equivalent, such as a new intended use/indications for use, change in processing cycles, etc.). The change may require some or all of the information needed for a new device. For additional information on the type of 510(k) submissions that are available to the manufacturer, refer to the “510(k) Paradigm” document listed in Section I.D of this guidance.
8. The name, address, and telephone number of the individual or individuals in the U.S. that may be contacted regarding the submission.
9. The name and address of each facility that will be used for manufacturing the washers and washer-disinfectors.

B. Table of Contents

The 510(k) should include a table of contents noting sections, titles, and pages. Each section should have its own table of contents.

C. Information required by the Safe Medical Devices Act of 1990

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 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).

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 descriptive information or performance or clinical testing information about the new and predicate devices(s). A summary shall be in a separate section and be clearly labeled as the 510(k) summary of safety and effectiveness.

Regulation establishing the requirements for the 510(k) summary, the 510(k) statement and the Truthful and Accurate Statement are delineated in 21 CFR 807.92, 807.93, and 807.87(j), respectively. FDA cannot complete the review of the 510(k) submission without the 510(k) summary or statement and the Truthful and Accurate Statement.

In addition, an Indications for Use Statement must be provided in a form recommended by FDA.

Sample copies of the 510(k) and Truthful and Accurate statements and the Indications for Use form may be obtained from DSMA.

D. Comparison of the Washer and Washer-Disinfector to the predicate Washer and Washer-Disinfector

In order to facilitate the finding of equivalence, the submission must include a detailed summary table comparing the washer and washer-disinfector to the predicate washer and washer-disinfector(s) with respect to physical properties, cycle parameters, reusable device compatibility, and intended use/indications for use [21 CFR 807.87(f)]. More than one device can be listed, but the device(s) chosen should be as close in intended use/indications for use and technology to the new device as possible. The information noted below lists examples of the

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information that can be included to show how the new device is both similar to and different from the legally marketed device. This information can be provided in a comparison table (re Example, Attachment 1).

1. Labeling (labels, instructions for use, promotional material) for the legally marketed device(s) to which substantial equivalence is claimed. To facilitate comparison, clear photographs, or other representations of the legally marketed device(s) should be included, unless the labeling has ample information.
2. Comparison of the intended use/indications for use listing both the similarities and differences of the new device and the predicate.
3. Comparison of the operational principles.
4. Comparison of the design, construction, components, accessories, process monitors, process parameters, etc.
5. Comparison of the performance claims of the new device to the predicate, such as cleaning and disinfection efficacies.

E. Other Data and Information

If data and/or information on file with another agency or as a device master file are cited, FDA must have access to all of the cited data. The 510(k) must include authorization from the submitter of the cited data enabling FDA to refer to the information on behalf of the 510(k) applicant.

F. Labels and Labeling

1. Proposed Labels and Labeling: The submission must contain proposed labels, labeling, and other promotional materials sufficient to describe the device, its indications for use/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 users manual, service manual, and any other information that accompanies the device.

2. Labeling Requirements: The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will concentrate on the following:

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

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

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3. User's Manual: The user's manual should contain at a minimum, where applicable, the following information:
  - a. the indications for use and intended use of the washer and washer-disinfector, such as cleaning and decontamination or disinfection of medical devices; a list of the types of medical devices which are compatible with the washer and washer-disinfector etc.;
  - b. 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 washer and washer-disinfector;
  - c. name and address of the manufacturer and/or distributor;
  - d. type and model designation;
  - e. installation instructions;
  - f. detailed operating or use instructions for all modes; the instructions should identify when various default or optional modes are applicable;
  - g. cleaning and disinfection instructions in the user's manual for the washer and washer-disinfector should compliment the cleaning and disinfection instructions provided by the reusable device manufacturer;
  - h. instructions on the use of enzymatic cleaners, detergents, lubricants, or germicides with the washer and washer-disinfector, such as preparation of the products for use with the washer and washer-disinfector or how the products are added to the cleaning or disinfection steps of the cycle, i.e., manual or automatic addition;
  - i. instructions on monitoring the germicide efficacy, if the disinfection cycle of the washer-disinfector uses a liquid chemical germicide. For any germicide that is reused, the instructions should state that the effectiveness of the germicide must be monitored on a regular basis, such as prior to each use, and that the user should not rely solely on days in use. The instructions should compliment the labeling instructions provided by the manufacturer of the liquid chemical germicide;
  - j. identification of the dilution factor of the germicide per machine cycle, if applicable;

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- k. a list of the generic types of detergents, enzymatic cleaners, and germicide which are compatible with the washer and washer-disinfector; the manual should include a warning that the user should follow the labeling for the detergent, enzyme cleaner, and germicide regarding conditions of preparation and use;
  - l. pre- and post-processing recommendation including any precleaning recommendations, if applicable;
  - m. error or fault indications, their causes, and response;
  - n. interpretation and use of indicator gauges, if applicable;
  - o. instructions for disinfecting the machine, itself, and the frequency that the self-disinfection cycle should be run, unless convincing data are provided in the submission showing that such a process is not needed;
  - p. any applicable warnings, hazards, and precautions;
  - q. other relevant information regarding the use of the washer and washer-disinfector, such as input water quality, temperature, water pressure, air pressure, flow rates, etc.;
  - r. a source of additional information should the user have questions.
4. Service Manual:
- a. a detailed description of all the tasks that must be accomplished to maintain the washer and washer-disinfector in proper operating condition, such as routine maintenance and inspection instructions, calibration, periodic microbiological sampling of all fluid paths and other communicating passages, etc.;
  - b. the schedule for these tasks, and;
  - c. identification of the individual who is responsible for the tasks (user or authorized service personnel).

G. Standards, Practices, Technical Reports

Appropriate or relevant voluntary industry or regulatory standards and recognized standards of practice, which the device meets, should be referenced including the year of publication. The applicant may certify that the device conforms to the stated standard or to certain sections of the standards. The applicant is obliged to meet the standard and maintain documentation of testing showing that the device

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meets the 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.

The following organizations may have standards or professional guidelines which are applicable to washers and washer-disinfectors intended for the processing of reusable medical devices: IEC, AAMI, AORN, APIC, CEN, ISO. It is recommended that manufacturers check with the organizations for any applicable voluntary standards or professional guidelines. The list of organizations, which may have voluntary standards or profession guidelines applicable to washers and washer-disinfectors is not all inclusive.

H. Description of the Washer and Washer-Disinfector

1. Overview

- a. Provide a complete overview of the washer and washer-disinfector. This description can consist of detailed drawings, photographs, and brochures. The interior dimensions and locations of the major components should be described.
- b. Provide a labeled, colored diagram for each of the cycles including water, enzyme cleaners, detergent, lubricant, air and disinfectant lines and reservoirs.
- c. Provide a labeled, colored diagram of the fluid pathway from the washer and washer-disinfector through all racks and other accessories.
- d. Describe all accessories which are compatible with the washer and washer-disinfector.

2. Intended Use(s) and Indications for Use: Provide a clear statement of the Intended Use(s) and Indications for Use of the device.

3. Design, Construction, Components, & Accessories

- a. Describe the materials used to construct the major components of the device. Provide the rationale for their selection.
- b. Indicate the device installation requirements such as electrical, plumbing, venting to the outside, etc.
- c. Describe the input requirements for the washer and washer-disinfector, such as water quality, water temperature, water

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pressure, volume, flow rates, electrical requirements, the pressure requirements, germicide temperature, compressed air quality, etc. Provide the rationale for each of the input requirements.

- d. Describe all manual or automatic controls, instrumentation, process monitors, recorders, vents, inputs, outlets, filters, and safety features. Provide the rationale for each.
  - e. Describe the delivery system(s) for the enzyme cleaner(s), detergent(s), lubricant(s), and the liquid chemical germicide(s), i.e. pumps, tubing, nozzle heads, connectors, etc. Provide the rationale for the design of the delivery system(s).
  - f. Describe all accessories marketed with the washer and washer-disinfector such as any hook-up adapters, wash racks, etc. Provide the rationale for the accessories.
4. Process Monitors
- a. 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, sensitivity).
  - b. Certify that all monitors reflect actual process conditions.
5. Process Parameters/Development
- a. Describe all process parameters. Parameters may include time, temperature, the water quality, preprocessing conditions, postprocessing 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. The process parameters should be based on sound scientific studies which show that each phase of the process achieves its stated purpose.
  - c. Describe all fault conditions related to each of the process parameters, including under what conditions a fault is detected and how the washer and washer-disinfector will respond. Provide the rationale for each.
- I. Performance Data

In general, washers and washer-disinfectors intended to reprocess reusable medical devices work in combination with detergents, enzyme cleaners, lubricants

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and in certain instances liquid chemical germicides to eliminate contamination. The electromechanical aspects of a washer and 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/Indications for Use, FDA believes that test data should show the ability of the device to produce a clean and decontaminated or disinfected reusable medical device prior to the reusable medical device use on a patient or exposure to a terminal process, such as sterilization.

1. Process Parameter Tests: Provide a summary of the data from tests which demonstrate that the machine achieves and maintains the specified physical process parameters. The testing should demonstrate the ability of the device to achieve and maintain the process parameters for each of the cycles under empty and full load conditions. The full chamber load should include representative types of devices identified in the labeling as being compatible with the washer and the accessory wash racks. Under full load testing, data should demonstrate that the reusable medical devices reach and maintain the recommended physical process parameters for each cycle, such as temperature, flow rates, pressures, etc. The empty and full chamber testing should be repeated a minimum of three runs to demonstrate repeatability of the controls.
2. Simulated-use Tests: The applicant should provide microbiological and chemical test data to demonstrate that the machine can deliver a cleaning or disinfection cycle for the contact conditions necessary to achieve the claimed Intended Use/Indications for Use when it is used in accordance with the directions for use. The simulated-use testing should evaluate the performance of the washer and washer-disinfector under worst case conditions. For example, worst case conditions for the washer and washer-disinfector could be testing at the minimum performance specifications for the cycles, such as minimum temperature, pressure, flow rates, contact times, etc., and just prior to any scheduled maintenance such as filter changes. If the disinfection step is achieved by means of a thermal process, it is recommended that the thermal process be at the minimum temperature and contact time. If the disinfection step is achieved through the use of a liquid chemical sterilant/disinfectant, it is recommended that the disinfectant/sterilant be at its minimum contact conditions, such as concentration, temperature and time. It is recommended that the simulated-use testing be conducted with reusable medical devices, which have been previously processed, rather than with new unused medical devices.

The degree of testing required for the washer and washer-disinfectors is dependent upon the claims made for the device. If the claim is only as a

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washer, then the manufacturer would only need to evaluate the cleaning step for each cycle. If the claim is both cleaning and disinfection, then the manufacturer would need to evaluate both the cleaning and disinfection steps for each cycle.

The simulated-use testing should include the following:

- a. the protocols for the methods by which the devices were contaminated/inoculated and treated prior to exposure to the processing steps;
- b. the protocols for validating the methods for contamination or inoculation of the devices prior to exposure to the processing steps, and the recovery methods used to evaluate the devices after exposure to the processing steps;
- c. replicate runs with devices, which represent the worst case challenge to the process; at least 3 replicate runs are recommended.
- d. a separate evaluation of the effectiveness of each processing step (cleaning, disinfection, rinsing, etc.) under worst case conditions;
  1. The evaluation of the cleaning parameters should demonstrate the effectiveness of the cleaning step independently of any other steps in the process. The manufacturer should define the endpoint for cleaning, provide the scientific rationale for the endpoint and show how it relates to clinical use. The testing should evaluate the ability of the cleaning step to remove a defined organic challenge. It is recommended that the organic challenge be representative of the types of soil to which devices are exposed during clinical use. The test data should demonstrate that the endpoint is consistently achieved for the devices identified in labeling as compatible with the washer and washer-disinfector. Since the microbial log reduction method to evaluate cleaning may not be directly related to a clinical endpoint for cleaning, it is unclear to FDA how the use of this method by itself will provide the necessary test data to show that the cleaning criteria have been met.
  2. The testing of the disinfection parameters for the washer-disinfector should be separate from the washing phase. The evaluation of the disinfection step should include devices which represent the greatest challenge to the disinfection

step. The devices should be inoculated with the appropriate test organism for the claimed level of disinfection. The recommended endpoints for the different disinfection claims are as follows: high level disinfection (thermal or chemical), 6-log reduction of an appropriate mycobacterium species; intermediate level disinfection, 3-log reduction of an appropriate mycobacterium species; low level disinfection, 6-log reduction of a suspension of vegetative organisms such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* or representatives of the Klebsiella-Enterobacter group. The test organisms should be suspended in an organic challenge and a quantified inoculum should be placed in locations on the devices that represent the greatest challenge. The inoculated sites should be dried prior to exposure to the disinfection step.

3. The evaluation of the rinse phase(s) should show that the rinse cycles remove the cleaning step residues to levels that do not interfere with the disinfection step and that all residues after the disinfection step have been reduced to levels which do not present a hazard to the patient or the end-user or interfere with a terminal process, such as sterilization.
  4. Testing should be conducted to demonstrate that the defined endpoints for other functions of the device, such as air drying and the self-disinfection cycle, are achieved. The test protocol for the self-disinfection cycle for the washer and washer-disinfector should reflect the use conditions that the device would experience in a hospital setting. For example, it is recommended that the testing be conducted after multiple cycles have been run in the machine for the period of time between recommended self-disinfection cycles. All areas, which could be a source of contamination, such as tubing, connections, filters, etc., should be microbiologically evaluated before and after the self-disinfection cycle.
3. In-use Testing: The in-use testing data should demonstrate that the washer and washer-disinfector achieve the claimed endpoints under actual clinical use. It is recommended that the test report include the following:
- a. The protocol should include a description of the methods used to evaluate the processed devices. It is recommended that the same

*Draft - Not for Implementation*

methods which were validated for the simulated-use testing be used for the in-use testing. The devices which represent the greatest challenge to the washer and washer-disinfector processes should be included in the in-use testing.

- b. It is recommended that the bioburden challenge (organic and microbial) to the cleaning and/or disinfection processes of the washer and washer-disinfectors be determined from clinically used devices. The devices included in the study should be processed according to any preprocessing recommendations in the labeling for the washer and washer-disinfector prior to placement in the device.

J. Toxicological Evaluation of Residues

1. Introduction

The 510(k) submission 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 washer and washer-disinfector and a toxicological evaluation of these residues. This can be satisfied by reviewing the available toxicity data of the particular residual chemical from animal toxicity studies sponsored by the manufacturer of the chemical or from published literature. This evaluation is needed to determine the potential health risk of the residues remaining on the device to the patient and the end user.

2. Hazard Evaluation

To ensure safe conditions of use of the medical device following processing, the applicant must present data which demonstrate that there are no residues remaining on the device or that the process cycle removes the residues to a nontoxic level. The applicant must also present data which demonstrate that there is no accumulation of residues over the use-life of the reusable medical device which could present a health risk to the patient and the user.

K. Software Documentation

The 510(k) submission should include a description of the validation of any software (or firmware). It is recommended 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, the washer and washer-disinfectors are considered to be in a "moderate" risk category as described in the

software guidance document.

L. Electrical Safety Requirements

The 510(k) should include a certification that the device meets any available standard for electrical safety, including electro-magnetic compatibility (EMC), if applicable. The FDA is in the process of recognizing IEC 60601. IEC 60601-2-045, "Safety Requirements for Washer/Disinfectors" is specific for these devices.

M. Comments

General questions regarding the submission of premarket applications 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

N. Reviewer Checklist for Washer, Washer-Disinfectors for Processing Reusable Medical Devices

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
	_____	service 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

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- \_\_\_\_\_ process parameters/development
- 5. \_\_\_\_\_ Descriptive Comparison to a Predicate
- 6. \_\_\_\_\_ Performance Data
- \_\_\_\_\_ physical tests
- \_\_\_\_\_ simulated-use tests
- \_\_\_\_\_ in-use tests
- 7. \_\_\_\_\_ Software Documentation
- 8. \_\_\_\_\_ Toxicological Evaluation of Residues
- \_\_\_\_\_ residue evaluation
- \_\_\_\_\_ hazard evaluation
- 9. \_\_\_\_\_ 510(k) summary or statement
- 10. \_\_\_\_\_ Truthful and Accurate Statement

References for the Washer and 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. ODE Blue Book Memorandum #K97-1 January 10, 1997. Deciding when to submit a 510(k) for a change to an existing device.
4. Rutala WA. Guideline for selection and use of disinfectants. *Am. J. Infect. Control* 1990 18:99-117.
5. Spaulding EH. Chemical disinfection and antisepsis in the hospital. *J. Hosp. Res.* 1972; 9:5-31.
6. 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/Indications for 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.