This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

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Guidance on

Premarket Notification [510(k)] Submissions

for

Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors

Intended for Use in Health Care Facilities

Infection Control Devices Branch

Division of General and Restorative Devices

August, 1993

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Preface

This guidance was developed by the Infection Control Devices Branch, Division of General and Restorative Devices (DGRD), 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 an endoscope washer/disinfector 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 an endoscope washer/disinfector. In this guidance, the term washer/disinfector will be used to refer to endoscope washers, washer/disinfectors, and disinfectors.

A safe and effective system to disinfect endoscopes intended for use in other than normally sterile areas of the body is important in preventing nosocomial infections. Comprehensive, scientifically sound criteria for the evaluation of endoscope washers, washer/disinfectors, and disinfectors is essential to help 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 endoscope washers, washer/disinfectors, and disinfectors in order to facilitate assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process.

The document expresses FDA's recommendations as of the date noted on the cover page. There is ongoing research and debate with regard to endoscope design and test methods. Despite this state of flux, FDA finds it necessary at this time to document its 510(k) submission criteria in order to expedite the availability of safe and effective washer/disinfectors. FDA expects that this document will stimulate and/or accelerate development of test methods and specific validation procedures by the scientific community and regulated industry. 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 page 17.

Advisory Concerning Accessories Used with Washer/Disinfectors

FDA regulates the accessories used with endoscope washer/disinfectors as medical devices. These include detergents, enzyme cleaners, and liquid chemical germicides that are intended for reprocessing medical devices. Liquid chemical germicides must be cleared under the 510(k) process. FDA is considering how to regulate the detergents and enzyme cleaners. The endoscope washer/disinfector, combined with legally marketed accessories, acts as a system to clean and disinfect endoscopes safely and effectively.

Since safe and effective cleaning and disinfection depends upon the combined performance of all elements in the system, FDA will not find an endoscope washer/disinfector substantially equivalent unless legally marketed, compatible accessories are identified in the washer/disinfector labeling, and the performance of the system is validated. The guidance provides detail on the validation process.

Manufacturers of products that are used in combination should work together to develop data to demonstrate that the products work as claimed in the system. This minimizes costs and time expended in obtaining market clearance for a device used in the system.

How does the washer/disinfector manufacturer have to address the accessories in their 510(k) notification? It depends on (1) the marketing status and labeling for the accessory, (2) who markets the accessory, and (3) the labeling for the washer/disinfector.

Generally, if the accessory is already a legally marketed medical device, then supplemental data must be submitted to FDA on performance of the accessory in the system, and the machine must be labeled for use with that accessory. If the accessory is not a legally marketed medical device, then comprehensive data must be submitted to establish substantial equivalence. For example, if the washer/disinfector indicates the use of Germicide X with their washer/disinfector for high level disinfection, and Germicide X is a legally marketed device, then data must be submitted validating use of Germicide X with the washer/disinfector. If Germicide X is not legally marketed, the data must meet all the relevant requirements of the FDA Guidance for Liquid Chemical Germicides, including performance in the washer/disinfector.

Until such time that the liquid chemical germicides with sterilization/high level disinfection claims are cleared for marketing by FDA, we are considering implementation of interim measures to facilitate the clearance of endoscope washer/disinfectors. FDA recommends that a person considering the submission of a 510(k) to FDA for an endoscope washer/disinfector should contact the Chief, Infection Control Devices Branch at (301) 594-1307 for the most up-to-date information concerning the status of our procedures.

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Guidance on Premarket Notification [510(k)] for Endoscope Washers, Washer/Disinfectors, and Disinfectors Used in Health Care Facilities

I. Introduction

A. Scope

This document establishes the 510(k) review requirements for endoscope washers, washer/disinfectors intended for use in health care facilities, e.g., hospitals, clinics, health care professional offices. The types of devices within this generic class are those washer/disinfectors which are electromechanical and may be microprocessor controlled. They are used to process endoscopes which are not normally used in sterile areas of the body, which can not be processed by a terminal sterilization process, or in which the recognized professional standard of practice permits high-level disinfection, when sterilization is not practicable. Some machines may not include a washing step.

Exclusions

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

B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in organizing premarket notifications for endoscope 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 premarket notifications.

C. Definitions

1. Bioburden: The naturally occurring microbial contamination on a medical device prior to exposure to a microbicidal process.

2. 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. The naturally occurring organic load is also known as bioburden.

3. Process and Product Qualification: Elements of the validation program consisting of selected engineering and microbiological demonstrations performed according to predefined protocols to show process reproducibility and product acceptability.

4. Precleaning: The removal of foreign material, e.g., organic or inorganic contaminants, from medical devices prior to a decontamination or disinfection process.

5. Process Residue: The microbicidal agent or by-products of the cleaning/disinfection process remaining on a medical device after completion of the cleaning/disinfection process.

6. Disinfection: The process that kills a defined scope of pathogenic organisms, not necessarily all microbial forms (e.g., bacterial endospores).

7. Disinfectant: A chemical agent that eliminates a defined scope of pathogenic organisms, not necessarily all microbial forms (e.g., bacterial endospores).

8. High Level Disinfectant: A germicide that kills all microbial pathogens, except large number of bacterial endospores, when used according to labeling.

9. 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.

10. Validation: A documented program which provides a high degree of assurance that a specific process will consistently meet its predetermined specifications and quality attributes.

11. 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).

D. 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 significant 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, if required 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 expeditiously 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. They should be of publication quality.

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 must include the protocol (objectives, precise description of materials, experimental methods, controls, observations, statistical methods and analyses, conclusions and comments. Do not submit raw data. Additional specific directions on protocols are included in 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 either must 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 of why data or information has not been supplied, or why alternative information is justified. Original 510(k)s that are grossly incomplete following a cursory review may be placed immediately on a hold status by notification to the applicant.

b. Under Section 807.87(h), the 510(k) must include any additional information regarding the device requested by FDA that is necessary to make a finding as to whether the device is substantially equivalent to a legally marketed device.

During the review period FDA may identify deficiencies in the submission that cause FDA to be unable to determine whether the device is equivalent. Notification of the existence and specifics of the deficiencies may be made either by telephone or in writing or both, depending upon the number and complexity of the deficiencies. Telephone contact will be used to clarify minor deficiencies.

The applicant may elect to do one of the following: respond to the deficiencies, submit a premarket approval application under section 515 of the act, formally withdraw the submission, or allow the submission to be administratively deleted if a response to the deficiencies is not received by FDA within 30 days.

Responses to the deficiency letters or telephone calls must be in writing and shall include a restatement of the deficiency (or copy of the deficiency letter) and the complete response. A response to deficiencies that is on its face grossly incomplete may not be considered for reevaluation and FDA may place the file on hold once again after the applicant is notified.

Amended information may raise additional significant questions, therefore, it is essential for the applicant to fully consider the deficiencies and provide a comprehensive response.

c. Nonclinical laboratory studies that will be submitted as part of a premarket notification submission should be conducted according to FDA GLP regulations (21 CFR Part 58). Compliance with these regulations supports the quality and integrity of the data submitted. Variances and the reason(s) for the variances from the GLP regulations should be noted in the submission.

E. Document Availability

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

- Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Germicides
- Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review

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 - endoscope washer/disinfector.
3. Classification name of the device - endoscope, accessories, cleaning for endoscope.
4. The establishment registration number, if applicable, or the sponsor, owner or operator submitting the premarket notification.
5. Class in which the device has been put under section 513 of the act, and the appropriate panel, if known. [78-FEB-II]
6. A statement explaining the purpose of the submission (e.g., new device, significant modification of device previously found equivalent (new intended use, material, or manufacturing process, etc.). Refer to 21 CFR §807.87(g) for additional requirements. The change may require some or all of the information needed for a new device.

7. A brief statement indicating the device is similar to and/or different from other legally marketed products of comparable type in commercial distribution. Data supporting that statement must be included (see below for more detail on performance data comparisons). It is important that the applicant provide specific descriptive information on the legally marketed devices(s) to which equivalence is claimed. Such information shall be provided in a separate section and include labeling for the equivalent device(s), and reference to a 510(k) notification or information indicating its pre-1976 status.

8. The name, address, and telephone number of the individual or individuals in the U.S. that may be contacted regarding the submission.

B. Table of Contents

The 510(k) shall include a table of contents noting section titles and pages. Each section shall be separated and begin with a section contents page if the section consists of several parts.

C. Labels and Labeling

1. Proposed Labels and Labeling: The submission should contain proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use. 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.

   Other portions are deferred for review to CDRH/Office of Compliance, Promotion and Advertising Policy Staff.

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

   a. the intended use of the washer/disinfector, such as cleaning and high-

level disinfection of endoscopes; a list of all brands and models of endoscopes which are compatible with the washer/disinfector; if generic descriptions, such as submersible, flexible, or rigid endoscopes, sigmoidoscopes, colonoscopes, etc. are used to describe endoscopes which are compatible with the endoscope washer/disinfector, the manufacturer will require to provide the rationale as to why generic descriptions are adequate;

b. limitations of use, that is, any special characteristics of certain types of endoscopes or their accessories which require special handling or which may not be adequately disinfected by the washer/disinfector;

c. name and address of the manufacturer;

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. the cleaning and disinfection instructions in the manual for the endoscope washer/disinfector must compliment the cleaning and disinfection instructions provided by the endoscope manufacturer.

h. how the detergent and disinfectant are prepared, added to the machine, reused, if applicable; and a description of how the disinfectant is added to the cycle;

i. if the detergent or disinfectant are reused, detailed instructions on monitoring the effectiveness of each; the instructions must state that test strips, which are labeled for use with the specific brand of chemical germicide, must be used on a regular basis, i.e., daily, to monitor the effective concentration of the germicide;

j. identification of the dilution factor of the disinfectant per machine cycle if the disinfectant is reused;

k. a description of any cycle counter used to monitor the disinfectant's reuse life; and how to set the disinfectant change warning light, i.e., when and how the cycle counter is reset;

l. a list of all detergents, enzyme cleaners, and disinfectants which are compatible with the washer/disinfector; the manual should include a warning that the user must follow the labeling for the detergent,

enzyme cleaner, and germicide regarding conditions of preparation and use;

m. pre- and post-processing recommendation including precleaning recommendations and final alcohol rinse or air drying, if applicable. (If the recommendation for the precleaning of endoscopes is not included in the manual, then the firm must provide justification with supporting data why precleaning is not necessary.) Also note in labeling that a sterile water final rinse is ideal, when practicable, but a water rinse of a determined low contamination quality followed by a 70% alcohol rinse may be acceptable when medically necessary;

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

o. interpretation and use of indicator gauges, if applicable;

p. instructions for disinfecting the machine itself, unless convincing data are provided showing that such a process is not needed, and the frequency that the self-disinfection cycle should be done;

q. any applicable warnings, hazards, and precautions;

r. other relevant information regarding the use of the washer/disinfector such as input water quality, water pressure, air pressure, use of sterile water for the rinses, alcohol rinses, etc. and a source of additional information should the user have a question; and

s. if the device is not a washer, precautions indicating the need for thorough precleaning and rinsing of the scope before placement into the machine.

4. Service Manual: Submit the service manual for the device which includes:

a. a detailed description of all the tasks that must be accomplished to maintain the washer/disinfector in proper operating condition, e.g., routine maintenance and inspections instructions, calibration, periodic microbiological sampling of all fluid paths and other communicating passages; etc.

b. the schedule for these tasks, and;

c. who is responsible for the tasks (user or authorized service personnel).

D. Standards, Practices, Technical Reports

Appropriate or relevant industry or regulatory standards and recognized standards of practice, which the device meets, should be referenced including the year of standards publication. The applicant may certify that the device meets the stated standard. The applicant then is obliged to meet the standard and maintain documentation of testing showing that the device meets the standard. The UL 544 standard may be applicable for the automated endoscope washer/disinfectors. The following organizations have guidelines which also may be applicable to automatic endoscope washer/disinfectors: AAMI, ISO, AORN, SGNA, ASGE, APIC. This list is not all inclusive.

E. Description of the Endoscope Washer/disinfector

1. Overview

   a. Provide a complete overview of the endoscope washer/disinfector. This description can consist of detailed drawings, photographs, and brochures. The description should include the method in which endoscopes are connected to the endoscope washer/disinfector. The interior dimensions and locations of all components should be indicated.

   b. Provide a labeled, blocked colored schematic of each cycle of the endoscope washer/disinfector including water, air and disinfectant lines, and all detergent, disinfectant, and water reservoirs.

   c. Provide a labeled, blocked colored schematic of the fluid pathway from the washer/disinfector through all compatible endoscopes.

   d. Describe all accessories, such as the adaptor hook-ups for endoscopes, which are compatible with the endoscope washer/disinfector.

2. Intended Use(s): Provide a clear description of the intended use(s) of the device (refer to the definition of intended use).

3. Design, Construction, Components, & Accessories

   a. Describe the materials used to construct all 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 endoscope washer/disinfector such as water quality, water pressure through the lines of the washer/disinfector and the channels of the endoscopes, electrical requirements, the pressures required to move fluids or air through the lines of the washer/disinfector and channels of the endoscopes,

compressed air quality, etc. Provide the rationale for each of the input requirements.

d. Describe all manual or automatic controls, instrumentation, recorders, vents inputs, outlets, filters, and safety features. Provide the rationale for each.

e. Describe the delivery system(s) for the detergent(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/disinfector such as endoscope hook-up adapters. Provide the rationale for the accessories.

4. Process Monitors

a. Provide a complete description 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, hardness of the water, preprocessing conditions, postprocessing conditions, etc. Identify the factors that affect the effectiveness of the processes and state how they are controlled.

b. Provide the specifications and basis for each process parameter. The process parameters must be based upon sound scientific studies, such as those describe in Section G and I, 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/disinfector will respond. Provide the rationale for each.

F. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed device to which substantial equivalence is claimed. More than one device can be listed, but the device(s) chosen should be as close in intended use and technology to the new device as possible. Provide the information noted below to show how the new device is both similar to and different than the legally marketed device. This information can be provided in a comparison table (re

Attachment 1). This information may be identical to that provided under Parts C and E. The applicant may wish to combine some or all of Parts C and E. Indicate how the differences may affect safety and effectiveness.

1. Provide labeling (labels, instructions for use, promotional material) for the legally marketed device(s) to which substantial equivalence is claimed. To facilitate comparison, also include clear photographs, or other representations of the legally marketed device(s), unless the labeling has ample information.

2. Compare and contrast the intended use of the new device to the predicate.

3. Compare all materials that come into contact with the fluid pathways of the device, for example endoscopes, wash chamber, tubing, etc. The precise materials of the new device, and if possible, the predicate should be identified to the extent possible.

4. Compare the operational principles.

5. Compare design, construction, components, accessories, process monitors, process parameters, etc.

G. Performance Data

In general, endoscope washer/disinfectors work in combination with detergents, enzyme cleaners, and liquid chemical germicides to eliminate scope contamination. The electromechanical aspects of an endoscope washer/disinfector can be evaluated on the basis of engineering specifications and tests. However, since the device must work in combination with other products as a system to achieve its intended use, FDA believes that test data must be produced showing the ability of the device to produce a disinfected scope.

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, These data should be from repeated runs using representative types of endoscopes (at least 3 runs/type) identified in the labeling as being compatible with the washer, i.e. gastroscopes, colonoscopes, sigmoidoscopes, etc.

2. Simulated-use Tests: The applicant must provide microbiological and chemical test data to demonstrate that the machine can deliver a high level disinfectant for the contact conditions necessary for high-level disinfection for all endoscopes identified in the labeling, when used in accordance with the directions for use. The simulated-use testing must evaluate the worst case conditions for the washer/disinfector, the disinfectant, and the endoscopes. For example, worst case conditions for the washer/disinfector could be

prolonged use at its minimum performance standards and just prior to any scheduled maintenance such as filter changes. The worst case conditions of the disinfectant could be an organically stressed disinfectant which is tested at the end of its shelf-life and reuse life against a resistant organism (e.g., a mycobacterium test species). The worst case conditions for an endoscope would be testing with an old scope as opposed to a new scope. The simulated-use testing must include the following:

a. the protocols for the methods of inoculating and handling of the endoscopes prior to processing and the protocols for validating the recovery methods (the draft ISO standard "Sterilization of health care products - Validation and routine control - Microbiological methods contains examples of acceptable validation methods);

b. replicate runs with representative types of endoscopes (at least 3 runs/type) as indicated by the labeling claims including a pediatric endoscope, if appropriate;

c. a separate evaluation of the effectiveness of each process step (washing, disinfection, rinsing, etc) over time either based upon the maximum number of days of reuse as stated upon the labeling for the disinfectant or as directed by the machine's labeling if the number of days of reuse is less than that stated on the labeling for the disinfectant. For example, microbiological and chemical testing would be done after the first cycle on day 0, at intervals during the testing period, and after the final cycle on the last day of the testing period as determined by either the germicide labeling or machine labeling. Reduced testing which concentrates on the initial and longest process days (e.g., day 0 and 14 day) must be justified such as demonstrating the linearity of the variables and performance.

    (1) an evaluation of the washing parameters to demonstrate the effectiveness of the washing step, including a fiberoptic examination of the endoscopes before and after washing to show that the washing cycle removes all visible organic soil;

    (2) determination of the effectiveness of disinfection phase of the washer/disinfector separate from the washing phase; this would require inoculation of the endoscopes at the start of the disinfection phase; refer to the FDA's Guidance for Liquid Chemical Germicides for the requirements for high level disinfection;

    (3) an evaluation of the rinse phase(s) to show that the washer/disinfector reduces any disinfectant residues to safe

levels and that the rinse cycles reduce any detergent residues to levels that do not interfere with the effectiveness of the disinfectant (see the discussion on Toxicological Evaluation of Residues);

(4) evaluation of any other parameters, i.e., alcohol rinse, air drying, self-disinfection process, etc. to demonstrate that they achieve their intended use, and;

(5) evaluation of the combined process including the effectiveness of the self-disinfection stage for the washer/disinfector, if applicable, to demonstrate that the washer/disinfector achieves its intended use; the testing protocol should reflect the use conditions that a washer/disinfector would experience in an endoscopy setting such as multiple cycles over the period of time recommended between self-disinfection or after the machine has set over the period of time recommended between self-disinfection; microbiologically evaluate the condition of all areas which could be a source of contamination before and after the self-disinfection cycle.

3. In-use Testing: Because of the increasing public health concern about the transmission of diseases such as AIDS, hepatitis, and tuberculosis, and due to the lack of correlation of simulations to actual use, FDA is requiring not only simulated-use testing but also in-use testing data.

The in-use (clinical) testing data must include an evaluation of the washer/disinfector to clean and high level disinfect various scopes taken from actual patient use. The test report must include:

a. the complete protocol indicating sampling, pretreatment (precleaning), handling, posttreatment (type of rinse), etc.;

b. evaluation of the major types of scopes indicated in labeling for the washer/disinfector;

c. a statistically derived sample size for each of the major types of scopes;

d. control and treated scopes for each of the major types of scopes;

e. collection of specific data on the scope including, but not necessarily limited to, scope type and condition of scope;

f. microbiological information such as the bioburden loads on the control and treated scopes prior to use, immediately after use, and just prior to

placement in the machine, and the extraction method;

g. a rigorous statistical evaluation, including explanation of any skips in the data (residual growth); and

h. comparative data on equivalent machines, if claims are made.

H. Software Documentation

Describe the validation of any software (or firmware). Refer to the FDA Software Reviewers Guide (available from FDA Division of Small Manufacturers Assistance) for 510(k) software documentation recommendations. Unless otherwise directed by FDA, automated endoscope washers are considered in the "major" risk category described in the software guidance.

I. Toxicological Evaluation of Residues

1. Introduction

The 510(k) submission must include an assessment of the level of any residues, (e.g. detergents, germicides) remaining on the endoscope after processing in the endoscope 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 endoscope to the patient and the user.

2. Hazard Evaluation

In ensuring safe conditions of use of the endoscope, the applicant must present data which demonstrate that there are no residues remaining on the endoscope 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 endoscope which could present a health risk to the patient and the user.

J. Summary of Information Regarding Safety and Effectiveness or Statement of Availability of Such Information

Under the Safe Medical Device Act of 1990, the 510(k) shall include either (1) an adequate summary of any information respecting safety and effectiveness on which equivalence is based, or (2) a statement that information regarding safety and effectiveness will be made available upon request to any person.

A summary shall be in a separate section and be clearly indicated as the summary respecting safety and effectiveness as required by the amended act.

Implementing regulations establishing the requirements for the summary and statement are forthcoming and will supersede this section. Notification of the requirements will be published in the Federal Register.

K. Comments

General questions regarding the submission of premarket applications should be directed to the Division of Small Manufacturers Assistance at (800) 638-2041.

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

FDA
Division of General and Restorative Devices, (HFZ-410)
Infection Control Devices Branch
1390 Piccard Drive
Rockville, MD 20850-4308

L. Checklist

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
	____	statement that the device is similar to and/or different from other products
	____	previous files referenced
	____	contact person
2.		Labeling
	____	proposed labels and labelings
	____	labeling requirements
	____	user's manual
	____	service manual
3.	____	Standards, Practices, Technical Reports
4.		Description of the Endoscope Washer/disinfector
	____	overview of the endoscope washer/disinfector

____ intended 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

7. ____ Software Documentation

8. Toxicological Evaluation of Residues

____ residue evaluation

____ hazard evaluation

9. ____ 510(k) summary or statement

Attachment 1

Comparison Table

Feature	New Device	Predicate
Labeling		
Intended use		
Identification of materials that come in contact with the fluid pathways		
Operational Principles		
Design, constructions, components		
Process Monitors: recorders, gauges, printouts, etc		
Process Parameters: time, temperature, input water quality, pressure, etc		
Software/firmware controls		
Cycle comparisons		
Accessories indicated in labeling: germicides detergents enzyme cleaners other		

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