K102244

STERIS®

DEC 3 2010

510(k) Summary
For
Reliance® Endoscope Processing System

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Summary Date: October 14, 2010

1. Device Name

Trade Name:	Reliance Endoscope Processing System
Common/usual Name:	Automated Endoscope Reprocessor
Classification Name:	21 CFR 876.1500 Endoscope Cleaning Germicide Accessories

2. Predicate Device

Reliance Endoscope Processing System K040049

3. Description of Device

The Reliance Endoscope Processing System is an economical, easy-to-use high level disinfection system intended to wash and high level disinfect up to two manually cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes and related accessories.

The system utilizes Reliance™ DG Dry Germicide, a proprietary, safe, and dry peracetic acid generating oxidative chemistry. The Reliance Endoscope Processing System was designed to be versatile in meeting the growing demands of the modern flexible endoscope processing department, while offering the highest level of patient and staff safety. The Reliance Endoscope Processing System is a combination of products that are used to wash and high level disinfect flexible endoscopes and their accessories.

- The **Reliance Endoscope Processor** is an electromechanical washer/high level disinfector with a microprocessor-based controller that provides for automated endoscope processing cycles and processor self-decontamination cycles.
- **Reliance DG Dry Germicide** is a proprietary, two-part, dry, single-use oxidative chemistry, designed to generate the high level disinfection solution upon automatic dilution in water within the Reliance Endoscope Processor.
- Optional washing is provided through the automated delivery of **Klenzyme Enzymatic Presoak and Cleaner** during the wash phase of the cycle.
- **CIP 200 Acid-Based Process and Research Cleaner**; a general cleaning agent, is used in one of the two self-decontamination cycles provided by the processor.
- Various accessories are available to accommodate the processing needs of specific endoscopes and endoscopic accessories.
- **Verify Reliance CI Process Indicator** is available to monitor for the presence of the Reliance DG active ingredient, peracetic acid.

The **Reliance Endoscope Processing Cycle** has the following features:

⇒ The first part of this cycle is an optional programmable **washing phase**. This phase consists of a wash that uses Klenzyme, followed by a rinse. The washing phase can be programmed on or off. In the "on" mode, the user can choose either one or two washing phases per processing cycle, and the wash time can be adjusted to be between 5 and 10 minutes. *The Reliance cleaning phase does not replace manual cleaning by the user.*

⇒ The second part is a **high level disinfection phase** that is non-optional and the parameters cannot be changed by the user. In this phase, the proprietary Reliance DG components, provided in a single use container, are dissolved with water at ~50°C for four minutes of generation time and circulated throughout the processor and through device lumens for 6 minutes of high level disinfection solution exposure time.

⇒ Following the high level disinfection phase, the Reliance Endoscope Processor removes the high level disinfection solution through a **rinse phase** which is non-optional and the parameters cannot be changed by the user. The processor filters the rinse water (as well as all of the water used throughout the cycle) through a 0.2 micron bacterial-retentive filter. It also incorporates an automatic internal integrity check of this filter at the end of each processing cycle. If the integrity check fails, an alarm alerts the user, and the processor does not complete the cycle.

⇒ The last step in the processing cycle is an **air purge phase** using HEPA-filtered air. The air purge helps to remove excess rinse water from the processed devices. The final air purge is preset to run for 4 minutes; additional air purge time may be selected by the operator.

⇒ The processor will print a detailed **cycle summary** at the end of each cycle that includes information such as processor number, cycle date, start and stop times, as well as phase parameters. With an optional bar code reader, the printouts can also include identification numbers for the operator, patient, device, doctor and procedure.

The processor features **two decontamination cycles** that are to be used without endoscopes in the processor:

⇒ The first, called D-SHORT, consists of hot water circulating through the processor for 10 minutes, followed by a 10-minute hot air purge. This cycle is to be run every 54 hours. D-SHORT is intended to prevent biofilm from forming.

⇒ The second, called D-LONG, consists of a cycle in which CIP 200 Acid-Based Process and Research Cleaner is added to hot water. The cleaning solution is then circulated through the processor for 20 minutes; this is followed by three rinses to remove the solution from the processor and a 10-minute hot air purge. D-LONG is to be used on those occasions when the D-SHORT cycle has not been run within the past 54 hours.

4. Intended Use

The Reliance Endoscope Processing System is intended for washing and high level disinfection of up to two manually cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50 – 57°C HLD Phase of the Endoscope Processing Cycle (4 minute generation sequence followed by a 6-minute exposure sequence).

5. Description of Safety and Substantial Equivalence

The Reliance Endoscope Processing System has the same technological characteristics as the predicate device.

A summary of performance testing applicable to both the proposed Reliance Endoscope Processing System and its predicate Reliance Endoscope Processing System is provided in the Table attached.

Non-clinical Tests: Germicide Efficacy

The Reliance Endoscope Processing System was developed and validated in accord with two primary FDA Guidance documents:

- Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants (2000), and
- Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers (1993).

A summary of this testing follows:

- **Reliance DG Dry Germicide Efficacy:**

Reliance DG Dry Germicide was tested and shown to generate an effective high level disinfection solution using the standard array of microbiological tests for germicidal efficacy. The following testing was performed at conditions of use that were worst case with respect to contact time, circulation, water hardness, temperature, artificial soiling, and germicide concentration (at or below the minimum effective dose of 9000 mg/L PAA minutes):

⇒ **Sporicidal**: Reliance DG Dry Germicide was proven to be sporicidal as defined by AOAC Sporicidal Activity Test with an *in situ* exposure time of 6 minutes. Confirmatory testing was completed successfully and supplemental confirmatory testing was completed in the Reliance Endoscope Processor. Potency was subsequently confirmed in the processor using Reliance DG Dry Germicide containers that were aged beyond the end of its shelf life.

⇒ **Tuberculocidal:** Reliance DG Dry Germicide was proven to be tuberculocidal as defined by the AOAC Tuberculocidal Activity Test with an exposure time of 6 minutes. Potency was subsequently confirmed using Reliance DG Dry Germicide aged beyond the end of its shelf life.

⇒ **Virucidal:** The Reliance Process was proven to reduce the viable population of poliovirus Type 1, adenovirus Type 5, and herpes simplex virus Type 1 by > 4 $\log_{10}$.

⇒ **Bactericidal:** Reliance DG Dry Germicide was proven to be bactericidal as defined by the AOAC Bactericidal Activity Test with an exposure time of 6 minutes at worst case conditions, whether performed *in situ* or *in vitro*.

⇒ **Fungicidal:** Reliance DG Dry Germicide was proven to be fungicidal as defined by the AOAC Fungicidal Activity Test with an exposure time of 6 minutes, whether performed *in situ* or *in vitro*.

Simulated-Use: Reliance DG Dry Germicide, at the minimum recommended dose, reproducibly achieved greater than a 6 $\log_{10}$ reduction of *Mycobacterium terrae* in triplicate trials within the Reliance Endoscope Processor for selected clinically relevant flexible endoscopes and their accessories. The test articles represented the range of most challenging devices, accessories, and processing situations.

In-Use: Reliance Endoscope Processing System was evaluated in an in use study in a US hospital. Three flexible endoscopes representing the range of types indicated in the product labeling were used in clinical procedures and processed according to instructions for use. In triplicate evaluations of each endoscope, no organisms were recovered after processing. Bioburden levels on the clinically used endoscopes after manual cleaning and before high level disinfection were determined to be as high as 10^5 CFU/device.

Non-clinical tests: Germicide Biocompatibility, Material Compatibility and Stability	• **Biocompatibility:** The Reliance chemical formulations, as supplied in packaging as well as in use dilutions, can be safely handled and used by customers. Residues that may remain on medical endoscopes and accessories are below established residue limits and do not pose a risk to patients. Safety statements in product labeling are appropriate to the potential risk. ⇒ **Reliance DG Dry Germicide, its components, reaction products, and residuals** remaining on medical devices were evaluated for biocompatibility and possible risks to users. Testing included acute oral and ocular toxicity tests, dermal irritation studies, *in vitro* bacterial mutation genotoxicity studies, sensitization tests, and *in vitro* cytotoxicity evaluations; literature reviews of raw material toxicity data were also performed. Certain components in the single-use container, which under normal use conditions never contact the user, have the potential for irritation or skin sensitization; therefore appropriate warnings and instructions are displayed on labeling for the unusual event of a spill or container breakage. ⇒ **Use dilution** reaches non-cytotoxic levels with minimal dilution. ⇒ Biocompatibility testing of **extracts from processed medical devices** demonstrated that no toxic residuals remain on devices under worst case circumstances. The test data indicate that the worst case residue levels for the components of maximum potential risk are far below the allowable limits. Furthermore, the processor final rinse water was found to be non-cytotoxic. • **Reliance Endoscope Processing System Material Compatibility:** The Reliance System was evaluated for its effect on intact medical devices, including flexible endoscopes and/or common materials of device construction. After 300 processing cycles, no deleterious effects were observed other than minor cosmetic changes. No functional changes in flexible endoscopes were observed. • **Reliance DG Dry Germicide Stability:** Reliance DG was tested and found stable for 18 months in the unopened moisture-resistant packaging at the stated conditions for storage. Once opened, the containers within each pouch are to be used within 2 weeks, or by the expiration date on the container, whichever comes first.

<table>
<tr><td>Non-clinical Tests: Processor Performance</td><td colspan="2">

• Reliance Endoscope Processor Performance

The critical process parameters for the processor (water temperature and volume, fresh Reliance DG Dry Germicide container detection, boot pressure, delivery of washing solutions and high level disinfection solution and water filter integrity testing) were each evaluated in replicate under worst case conditions and found to be within required specifications.

Each processor phase or cycle was separately evaluated and documented to be effective under worst case conditions:

⇒ Validation of the washing phase of the Endoscope Processing Cycle documented that after the shortest possible washing phase, devices pre-soiled with a combination of eggs, blood, mucin and serum in saline: 1) were visually clean, and 2) achieved greatly reduced yield of extractable protein per cm^2 device area (assayed to be reduced from >173 to < 5 $\mu g/cm^2$).

⇒ Validation of the high level disinfection phase of the Endoscope Processing Cycle was performed through a simulated-use study in challenging clinically relevant endoscopes, as well as in an in-use study.

⇒ The rinse phase of the endoscope processing cycle was shown to be effective. Evaluations of extracts of devices exposed to worst case conditions in the Endoscope Processing Cycle documented that levels of residuals remaining on devices were far below allowable limits and were not cytotoxic.

⇒ The air purge phase was validated to confirm the ability to remove rinse water from processed medical devices.

⇒ The filter integrity test system of the processor was documented to reliably detect filter failure.

⇒ The two self-decontamination cycles were shown to be effective as follows:

- D-LONG cycle – can disinfect the Reliance Endoscope Processor after a high level challenge with *Pseudomonas aeruginosa* followed by a 5 day inactive period;
- D-SHORT cycle – can kill bacteria that have potential to form biofilm.

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<tr><td rowspan="5">Reliance Endoscope Processor is certified to the following electrical standards</td><td>ANSI/UL -61010-1, 2nd Ed.,</td><td>Electrical equipment for measurement, control and laboratory use Part 1, 2nd Edition</td></tr>
<tr><td>CAN/CSA C22.2 61010-1, 2nd Ed.</td><td>Electrical equipment for measurement, control and laboratory use Part 1, 2nd Edition</td></tr>
<tr><td>IEC 61010-1:2001</td><td>Safety requirements for electrical equipment for measurement, control and laboratory use, Part 1: General requirements,</td></tr>
<tr><td>IEC 61010-2-40, 1st Ed.</td><td>Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials</td></tr>
<tr><td>IEC 61326-1:2005, 1st Ed.</td><td>Electrical equipment for measurement, control and laboratory use, EMC requirements Part 1: General requirements</td></tr>
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
Senior Director, Regulatory Affairs
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5960 Heisley Road
Mentor, Ohio 44060

Re: K102244
Trade/Device Name: Reliance® Endoscope Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: NZA
Dated: October 26, 2010
Received: October 27, 2010

DEC - 3 2010

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

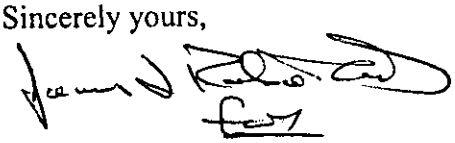
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Reliance® Endoscope Processing System

Indications for Use:

The Reliance Endoscope Processing System is intended for washing and high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50 – 57°C HLD Phase of the Endoscope Processing Cycle (4 minute generation sequence followed by a 6-minute exposure sequence).

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F Claxton-Wells

vision Sign-Off)
vision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K102244