March 10, 2022

STERIS Corporation
Jennifer Nalepka
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K220361
Trade/Device Name: Reliance Endoscope Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NZA
Dated: February 7, 2022
Received: February 8, 2022

Dear Jennifer Nalepka:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220361

Device Name
Reliance Endoscope Processing System

Indications for Use *(Describe)*

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 bronchoscopes, GI flexible endoscopes including duodenoscopes, 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).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For
Reliance Endoscope Processing System

STERIS
5960 Heisley Road
Mentor, OH 44060
Telephone: 440-354-2600

Contact: Jennifer Nalepka
Lead Regulatory Affairs Specialist
Telephone: 440-392-7458

Summary Date: March 10, 2022

Premarket Notification Number: K220361

1. Device Name

Trade Name:	Reliance Endoscope Processing System
Device Classification:	Class II
Common/usual Name:	Automated Endoscope Reprocessor
Classification Name:	Accessories, Germicide, Cleaning, For Endoscopes
Classification Number:	21 CFR 876.1500
Product Code:	NZA

2. Predicate Device

Reliance Endoscope Processing System, K203223

3. Description of Device

The Reliance Endoscope Processing System is a high level disinfection system that can wash and high level disinfects up to two manually precleaned, 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 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 washing 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 disinfecting solution exposure time.
- Following the high level disinfection phase, the Reliance Endoscope Processor removes the high level disinfecting 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/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 bronchoscopes, GI flexible endoscopes including duodenoscopes, 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. Technological Characteristic Comparison Tables

The Reliance Endoscope Processing System (EPS) is the same as the predicate device; this submission is provided to demonstrate the validity of the system's ongoing use to process duodenoscopes. A comparison between the predicate and proposed devices can be found in **Tables 1** and **2.**

Table 1. Technological comparison for Reliance EPS

Feature	Proposed Device Reliance EPS	Predicate Device Reliance EPS K203223	Comparison
Intended Use / 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 bronchoscopes, GI flexible endoscopes, including duodenoscopes, 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).	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 bronchoscopes, GI flexible endoscopes, including duodenoscopes, 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).	Identical
Operating Principles/ Technology	The Reliance EPS and its integrated endoscope processing support provide for delivery of solutions and fluids to endoscopes and their accessories. Klenzyme and Reliance DG are introduced into the Reliance EPS to provide washing and high level disinfection. Decontamination cycles (D-Long with CIP-200	The Reliance EPS and its integrated endoscope processing support provide for delivery of solutions and fluids to endoscopes and their accessories. Klenzyme and Reliance DG are introduced into the Reliance EPS to provide washing and high level disinfection. Decontamination cycles (D-Long with CIP-200	Identical

Feature	Proposed Device Reliance EPS	Predicate Device Reliance EPS K203223	Comparison
	and D-Short) are used to prevent biofilm formation in the Reliance EPS Processor and ensure effective processing following periods of processor inactivity.	and D-Short) are used to prevent biofilm formation in the Reliance EPS Processor and ensure effective processing following periods of processor inactivity.	
Process Parameters	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temperature • Cleaning solution and Reliance DG concentration • Water filter integrity	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temperature • Cleaning solution and Reliance DG concentration • Water filter integrity	Identical
Process Monitors	• Control Handle Boot pressure alarms if pressure too low to process, or if too high and could potentially damage scopes (specification 6.5 – 10.5 PSI). • Detection of a fresh Reliance DG container in every processing cycle Cleaning Solution level monitored; alarm indicates when container does not have sufficient amount to complete cycle • Temperature alarms if outside of range • Water filter integrity test at end of each high level disinfection cycle.	• Control Handle Boot pressure alarms if pressure too low to process, or if too high and could potentially damage scopes (specification 6.5 – 10.5 PSI). • Detection of a fresh Reliance DG container in every processing cycle Cleaning Solution level monitored; alarm indicates when container does not have sufficient amount to complete cycle • Temperature alarms if outside of range • Water filter integrity test at end of each high level disinfection cycle.	Identical
Design Features	• Intended for use with Reliance DG only • Microprocessor controlled • Internal components constructed of stainless steel, silicone, polypropylene and PVDF. • Processor provides 0.2 micron filtered water for washing, disinfection and rinsing	• Intended for use with Reliance DG only • Microprocessor controlled • Internal components constructed of stainless steel, silicone, polypropylene and PVDF. • Processor provides 0.2 micron filtered water for washing, disinfection and rinsing	Identical

Feature	Proposed Device Reliance EPS	Predicate Device Reliance EPS K203223	Comparison
	• Automated injection of cleaning solutions • Automated generation and delivery of high level disinfecting solution • Air intake for Air Purge is HEPA filtered	• Automated injection of cleaning solutions • Automated generation and delivery of high level disinfecting solution • Air intake for Air Purge is HEPA filtered	
Cycle Description	• Optional: Wash 1 with 1 rinse or Wash 2 with 1 rinse o Wash time can be adjusted to be between 5 and 10 minutes, 40 second rinse • Additional "smart rinse" occurs after optional wash if boot pressure < 7.0 psi is detected during the heating phase prior to generation phase: 40 second rinse • HLD Generation: 4 minutes • HLD Exposure: 6 minutes • Rinse 1: 40 seconds • Rinse 2: 40 seconds • Air purge o Can be adjusted to be between 4 and 30 minutes	• Optional: Wash 1 with 1 rinse or Wash 2 with 1 rinse o Wash time can be adjusted to be between 5 and 10 minutes, 40 second rinse • Additional "smart rinse" occurs after optional wash if boot pressure < 7.0 psi is detected during the heating phase prior to generation phase: 40 second rinse • HLD Generation: 4 minutes • HLD Exposure: 6 minutes • Rinse 1: 40 seconds • Rinse 2: 40 seconds • Air purge o Can be adjusted to be between 4 and 30 minutes	Identical
Maintenance Requirements	• D-SHORT decontamination cycle required every 54-hours • D-LONG decontamination cycle required if D-SHORT not performed within past 54 hours • Periodic cleaning of debris screen and spray arms • Periodic replacement of water and air filters	• D-SHORT decontamination cycle required every 54-hours • D-LONG decontamination cycle required if D-SHORT not performed within past 54 hours • Periodic cleaning of debris screen and spray arms • Periodic replacement of water and air filters	Identical
Accessories			
Chemical Indicator	VERIFY Process Indicator for Reliance EPS, K063285. Peracetic acid dose indicator for routine monitoring of Reliance EPS using Reliance DG.	VERIFY Process Indicator for Reliance EPS, K063285. Peracetic acid dose indicator for routine monitoring of Reliance EPS using Reliance DG.	Identical

Feature	Proposed Device Reliance EPS	Predicate Device Reliance EPS K203223	Comparison
	Chemical reaction on indicator pad to produce color change.	Chemical reaction on indicator pad to produce color change.	
Flow Units	Flow units are required only for scope channels that do not open in the endoscope control handle or mechanical action is required for valve operation. Eleven Flow Units are available.	Flow units are required only for scope channels that do not open in the endoscope control handle or mechanical action is required for valve operation. Eleven Flow Units are available.	Identical

Table 2. Technological comparison of Reliance DG Dry Germicide

Feature	Proposed Device Reliance DG Dry Germicide	Predicate Device Reliance DG Dry Germicide	Comparison
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 bronchoscopes, GI flexible endoscopes, including duodenoscopes, 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).	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 bronchoscopes, GI flexible endoscopes, including duodenoscopes, 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).	Identical.
Germicide Exposure Time (min) for HLD	10 minutes (4-minute generation sequence followed by a 6-minute exposure sequence)	10 minutes (4-minute generation sequence followed by a 6-minute exposure sequence)	Identical
Use Temperature	50 – 57°C	50 – 57°C	Identical
Reuse	Single use	Single use	Identical
Human Factors	Dispensed ready to use. Container opened automatically by the processor, limiting user exposure to the germicide.	Dispensed ready to use. Container opened automatically by the processor, limiting user exposure to the germicide.	Identical
Physical and Chemical Properties			
Container	Single-use, 2 Compartment Container	Single-use, 2 Compartment Container	Identical
Composition, Packaged product	Dry/Dry	Dry/Dry	Identical

Feature	Proposed Device Reliance DG Dry Germicide	Predicate Device Reliance DG Dry Germicide	Comparison
Active Ingredient	Peracetic acid, generated *in situ*	Peracetic acid, generated *in situ*	Identical
Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls[1] -hydroxyl radicals produced from PAA are bactericidal[2] -PAA damages the viral capsid and viral nucleic acid[3],[4]	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls[1] -hydroxyl radicals produced from PAA are bactericidal[2] -PAA damages the viral capsid and viral nucleic acid[3,4]	Identical
Rinses	2 rinses, 40 seconds each, with 0.2µ filtered water.	2 rinses, 40 seconds each, with 0.2µ filtered water.	Identical
Microbial Efficacy			
Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogenes*	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogenes*	Identical
Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogenes*	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogenes*	Identical
Fungicidal Activity of Disinfectants AOAC Official Method 955.17	Solution is fungicidal. *Trichophyton mentagrophytes*	Solution is fungicidal. *Trichophyton mentagrophytes*	Identical
Use-Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Identical
EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	Process conditions are virucidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1	Process conditions are virucidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1	Identical

[1] Block, S. ed., Disinfection, Sterilization, and Preservation. 5th edition, 2001
[2] Clapp et al., Free Rad. Res., (1994) 21:147-167
[3] Maillard et al., J. Med Microbiol (1995) 42:415-420
[4] Maillard et al., J. Appl. Bacteriol. (1996) 80:540-554
[5] McDonnell et al. J. AOAC International (2000) 83:269-275

Feature	Proposed Device Reliance DG Dry Germicide	Predicate Device Reliance DG Dry Germicide	Comparison
Tuberculocidal Activity of Disinfectants AOAC Official Method 965.12	Solution is tuberculocidal. *Mycobacterium bovis*	Solution is tuberculocidal. *Mycobacterium bovis*	Identical
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae*	Solution is tuberculocidal *Mycobacterium terrae*	Identical
Simulated-Use Test	Meets efficacy requirement *Mycobacterium terrae*	Meets efficacy requirement *Mycobacterium terrae*	Identical
Biocompatibility			
Cytotoxicity Device Extracts	Non-cytotoxic per ISO 10993-5	Non-cytotoxic per ISO 10993-5	Identical
Residue Reduction	Automatic within the Reliance Endoscope Processor, 2 x 15 L – 0.2 µ filtered water rinses after HLD cycle effectively reduces germicide residues to safe levels.	Automatic within the Reliance Endoscope Processor, 2 x 15 L – 0.2 µ filtered water rinses after HLD cycle effectively reduces germicide residues to safe levels.	Identical
Device Material Compatibility	Compatible with intended flexible endoscopes and accessories established through testing finished medical devices. No device functional changes. Some materials show cosmetic changes such as fading of external markings but all remained legible, and bleaching of black anodized aluminum without harm to the base material.	Compatible with intended flexible endoscopes and accessories established through testing finished medical devices. No device functional changes. Some materials show cosmetic changes such as fading of external markings but all remained legible, and bleaching of black anodized aluminum without harm to the base material.	Identical

6. Summary of Non-Clinical Testing

Shown in **Table 3** is the new testing that was performed to evaluate the device.

Table 3. Summary of verification activities

Test	Purpose	Acceptance Criteria	Result
Fit test	Confirm components made with new raw material can be installed without interference or issue	No impact on fit of components made with new raw material as compared to device originally cleared in K040049.	PASS
Technical specifications	Confirm specifications of new raw material	Technical specifications must be the same or better than current raw material as compared to device originally cleared in K040049.	PASS
Biocompatibility and Chemical Compatibility	Confirm biocompatibility and chemical compatibility	Biocompatibility and chemical compatibility are unaltered as described in ANSI/AAMI/ISO 10993-1:2018 and ANSI/AAMI/ISO 10993-5:2009.	PASS

7. Summary of Clinical Testing

Clinical testing was not performed because it is not applicable for this submission.

8. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K203223), Class II (21 CFR 876.1500), product code NZA.