December 2, 2024

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

Re: K243433
Trade/Device Name: enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: November 5, 2024
Received: November 5, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katharine Segars -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243433

Device Name

enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System

Indications for Use *(Describe)*

The enspire™ 3000 Series Cleaning and Liquid Chemical Sterilant Processing System is intended to effectively provide a pressure monitor, clean, provide liquid chemical sterilization, rinse, and air purge validated immersible, reusable, semicritical, heat sensitive medical devices such as flexible endoscopes and their accessories.

The validated cleaning process replaces cleaning for endoscopes other than duodenoscopes. Manual cleaning of duodenoscopes according to the manufacturer's written instructions for use is required prior to placement in the enspire™ 3000 Series Processor.
The enspire™ 3000 Series Processor uses only Revital-Ox 2X Concentrate Enzymatic detergent to clean and S40 Sterilant Concentrate to liquid chemically sterilize medical devices. It automatically dilutes the S40 Sterilant Concentrate to its use dilution (> 1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 46.6 to 55°C and rinses the load with 0.2-micron filtered water.

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.

510(k) Summary
enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System
K243433

STERIS Corporation
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Contact: Jennifer Nalepka
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Summary Date: November 27, 2024

1. Device Name

Trade Name:	enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System
Device Classification:	Class II
Common/usual Name:	Endoscope Cleaner and Reprocessor
Classification Name:	Endoscope and Accessories
Classification Number:	21 CFR 876.1500
Product Code:	FEB

2. Predicate Device

enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System, K230930

3. Description of Device

The enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS) is a medical device processing system used for cleaning and liquid chemically sterilizing immersible, reusable, semi-critical, heat-sensitive devices such as flexible endoscopes and their accessories. The system consists of the enspire 3000 Processor, Revital-Ox 2X Concentrate Enzymatic Detergent, S40 Sterilant Concentrate and Max Flow Connectors.

The enspire 3000 Cleaning and LCSPS is an automated, self-contained device for the effective cleaning and liquid chemical sterilization of semi-critical medical devices and their accessories. The devices will not require manual cleaning prior to processing in the enspire 3000 Processor with the exception of duodenoscopes which must be manually cleaned per the manufacturer's instructions for use. In addition, prior to placement in the enspire 3000 processor, the device will undergo a manual leak test and the user will ensure the lumens are not blocked. If the device has internal channels or lumens, Max Flow Connectors are used to facilitate the delivery of detergent, sterilant use-solution and rinse water to internal channels.

Once the device is positioned in the enspire 3000 processor, the unit will create and maintain the conditions necessary for effective cleaning and liquid chemical sterilization of the load. At the beginning of the processing cycle, automated pressure monitoring is performed to confirm the integrity of the flexible endoscope throughout the process. The enspire 3000 processor maintains inflation of the processed device to prevent ingress of fluid during processing and the pressure monitoring is repeated at the end of the processing cycle to ensure that the device is leak tight after cleaning and liquid chemical sterilization. At the end of the processing cycle, the cleaned and liquid chemically sterilized devices are rinsed with 0.2 micron filtered potable water followed by a HEPA-filtered air purge to aid in drying the endoscope. The processor, which is computer controlled and continually monitored, provides documentation of each cycle.

The enspire 3000 processor utilizes Revital-Ox 2X Concentrate Enzymatic Detergent for cleaning and S40 Sterilant Concentrate for liquid chemical sterilization. S40 Sterilant

Concentrate is a single use chemical sterilant concentrate; its active ingredient, peracetic acid, is combined with inert ingredients (builders) to form a use dilution which inhibits corrosion of metals, polymers and other materials.

Proposed Modification

The modification being proposed for clearance through this premarket notification is for a change in materials of the Chemical Delivery System (CDS) of the enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS). The CDS is designed to hold the S40 Sterilant Concentrate cup and puncture the cup at the start of the liquid chemical sterilization phase of the cycle so that the chemistry can be mixed with water to form the use dilution. The CDS assembly consists of a cup receiver and lid, puncture needle, pneumatic cylinder, and door. The cup receiver and lid are made from acrylonitrile butadiene styrene (ABS) plastic and these parts will be changed to be made from polysulfone (PS).

4. Indications for Use

The enspire™ 3000 Series Cleaning and Liquid Chemical Sterilant Processing System is intended to effectively provide a pressure monitor, clean, provide liquid chemical sterilization, rinse, and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices such as flexible endoscopes and their accessories.

The validated cleaning process replaces cleaning for endoscopes other than duodenoscopes. Manual cleaning of duodenoscopes according to the manufacturer's written instructions for use is required prior to placement in the enspire™ 3000 Series Processor.

The enspire™ 3000 Series Processor uses only Revital-Ox 2X Concentrate Enzymatic detergent to clean and S40 Sterilant Concentrate to liquid chemically sterilize medical devices. It automatically dilutes the S40 Sterilant Concentrate to its use dilution (> 1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 46.6 to 55°C and rinses the load with 0.2-micron filtered water.

5. Technological Characteristic Comparison Tables

Table 1. Predicate Device Comparison Table

Feature	Proposed Device K243433 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device K230930 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Comparison
Intended Use Indications for Use	The enspire™ 3000 Series Cleaning and Liquid Chemical Sterilant Processing System is intended to effectively provide a pressure monitor, clean, provide liquid chemical sterilization, rinse, and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices such as flexible endoscopes and their accessories. The validated cleaning process replaces cleaning for endoscopes other than duodenoscopes. Manual cleaning of duodenoscopes according to the manufacturer's written instructions for use is required prior to placement in the	The enspire™ 3000 Series Cleaning and Liquid Chemical Sterilant Processing System is intended to effectively provide a pressure monitor, clean, provide liquid chemical sterilization, rinse, and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices such as flexible endoscopes and their accessories. The validated cleaning process replaces cleaning for endoscopes other than duodenoscopes. Manual cleaning of duodenoscopes according to the manufacturer's written instructions for use is required prior to placement in the	Identical

Feature	Proposed Device K243433 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device K230930 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Comparison
	enspire™ 3000 Series Processor. The enspire™ 3000 Series Processor uses only Revital-Ox 2X Concentrate Enzymatic detergent to clean and S40 Sterilant Concentrate to liquid chemically sterilize medical devices. It automatically dilutes the S40 Sterilant Concentrate to its use dilution (> 1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 46.6 to 55°C and rinses the load with 0.2-micron filtered water.	enspire™ 3000 Series Processor. The enspire™ 3000 Series Processor uses only Revital-Ox 2X Concentrate Enzymatic detergent to clean and S40 Sterilant Concentrate to liquid chemically sterilize medical devices. It automatically dilutes the S40 Sterilant Concentrate to its use dilution (> 1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 46.6 to 55°C and rinses the load with 0.2-micron filtered water.	
Operating Principles / Technology	• Microprocessor controlled unit with a fixed basin. • The processor lid is opened with hands-free lid operation. • Devices with internal lumens are interfaced with the processor using connectors, i.e. Max Flow Units • Instrument pressure monitoring performed at beginning and end of cycle to monitor endoscope integrity • Revital-Ox 2X Concentrate Enzymatic Detergent is dispensed for the cleaning phase of the processing cycle. • Single-use cup of S40 Sterilant Concentrate is placed in a specialized compartment; when the processor fills with water during the LCS phase of the processing cycle, it creates the sterilant use dilution • The processor automatically rinses the load with 0.2 micron filtered water after cleaning and LCS phases • HEPA-filtered air purge to aid in drying	• Microprocessor controlled unit with a fixed basin. • The processor lid is opened with hands-free lid operation. • Devices with internal lumens are interfaced with the processor using connectors, i.e. Max Flow Units • Instrument pressure monitoring performed at beginning and end of cycle to monitor endoscope integrity • Revital-Ox 2X Concentrate Enzymatic Detergent is dispensed for the cleaning phase of the processing cycle. • Single-use cup of S40 Sterilant Concentrate is placed in a specialized compartment; when the processor fills with water during the LCS phase of the processing cycle, it creates the sterilant use dilution • The processor automatically rinses the load with 0.2 micron filtered water after cleaning and LCS phases • HEPA-filtered air purge to aid in drying	Identical

Feature	Proposed Device K243433 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device K230930 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Comparison
Process Parameters	Standardized cycle parameters cannot be altered by the operator. The critical process parameters monitored during processing: • Detergent dilution and cleaning time • Detergent dilution temperature • Use dilution contact time • Use dilution temperature	Standardized cycle parameters cannot be altered by the operator. The critical process parameters monitored during processing: • Detergent dilution and cleaning time • Detergent dilution temperature • Use dilution contact time • Use dilution temperature	Identical
Process Monitors	• The processor monitors and controls the detergent and LCS use dilution phase times. • Cycle record documents successful cycle completion or identifies fault if cycle aborts • Alarms if RTDs indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if pressure transducer indicates circulation pressure is out of specification • Alarms if internal water filter failed Filter Integrity Test. • Alarms if loss of pressure inside of endoscope indicates a leak	• The processor monitors and controls the detergent and LCS use dilution phase times. • Cycle record documents successful cycle completion or identifies fault if cycle aborts • Alarms if RTDs indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if pressure transducer indicates circulation pressure is out of specification • Alarms if internal water filter failed Filter Integrity Test. • Alarms if loss of pressure inside of endoscope indicates a leak	Identical
Design Features	• Unalterable and standardized Processing Cycle for cleaning and liquid chemical sterilization • Filter Integrity Test for demonstrating 0.2 micron water filter maintains functionality after replacement or power outage • Automated stand-alone system with one reprocessing basin • Basin lid features a rotating spray arm. • Intended for use with only Revital-Ox 2X Concentrate Enzymatic Detergent and S40	• Unalterable and standardized Processing Cycle for cleaning and liquid chemical sterilization • Filter Integrity Test for demonstrating 0.2 micron water filter maintains functionality after replacement or power outage • Automated stand-alone system with one reprocessing basin • Basin lid features a rotating spray arm. • Intended for use with only Revital-Ox 2X Concentrate Enzymatic Detergent and S40	Identical

Feature	Proposed Device K243433 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device K230930 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Comparison
	Sterilant Concentrate • Automated delivery of Revital-Ox 2X Concentrate Enzymatic Detergent • Automated dilution and delivery of S40 Sterilant • Processor provides 0.2 micron filtered water for liquid chemical sterilization and rinsing after LCS phase of Processing Cycle • Compressed air for processor during drain sequence is filtered through a 0.2 micron membrane air filter • Includes a bar code scanner; employs touchscreen display interface; has USB drive for electronic cycle download; facilitates use of a web-based data management system. • Separate, optional printer	Sterilant Concentrate • Automated delivery of Revital-Ox 2X Concentrate Enzymatic Detergent • Automated dilution and delivery of S40 Sterilant • Processor provides 0.2 micron filtered water for liquid chemical sterilization and rinsing after LCS phase of Processing Cycle • Compressed air for processor during drain sequence is filtered through a 0.2 micron membrane air filter • Includes a bar code scanner; employs touchscreen display interface; has USB drive for electronic cycle download; facilitates use of a web-based data management system. • Separate, optional printer	
Cycle Parameters			**Comparison**
Integrity Test	Performed at beginning and end of cycle	Performed at beginning and end of cycle	Identical
Pre-Rinse Phase	Pre-filtered water at 40°C	Pre-filtered water at 40°C	Identical
Incoming Water Temp	37 - 45°C	37 - 45°C	Identical
Cleaning Phase Temperature	> 42.2°C	> 42.2°C	Identical
Cleaning Phase Exposure Time	2 minutes	2 minutes	Identical
Rinse Phase after Cleaning	Pre-filtered water below 55°C	Pre-filtered water below 55°C	Identical
HLD or LCS Phase Temperature Range	LCS: 46.6 - 50°C	LCS: 46.6 - 50°C	Identical
HLD or LCS Phase Exposure	6 minutes	6 minutes	Identical

Feature	Proposed Device K243433 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device K230930 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Comparison
Time			
Rinse Phase after HLD or LCS	Hot potable tap water that is pre-filtered then filtered through a 0.2 micron bacterial retentive filter	Hot potable tap water that is pre-filtered then filtered through a 0.2 micron bacterial retentive filter	Identical
Number of rinses	2 after Cleaning Phase 2 after LCS Phase	2 after Cleaning Phase 2 after LCS Phase	Identical
Alcohol Rinse	No	No	Identical
Air Purge	Yes	Yes	Identical
Approximate Cycle Time	38 minutes	38 minutes	Identical
Accessories			**Comparison**
Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	Identical
High Level Disinfectant	N/A	N/A	Identical
Liquid Chemical Sterilant	S40 Sterilant Concentrate	S40 Sterilant Concentrate	Identical
Connectors	Max Flow Connectors	Max Flow Connectors	Identical
Chemical Indicator	Celerity Chemical Indicator for enspire 3000 Cleaning and Liquid Chemical Sterile Processing System	Celerity Chemical Indicator for enspire 3000 Cleaning and Liquid Chemical Sterile Processing System	Identical
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant	VERIFY Spore Test Strip for S40 Sterilant	Identical
Operator Maintenance	Periodic replacement of detergent, water filters and air filter. Periodic replacement of printer tape if using the external printer option. Cleaning outside of the unit and basin drain screen as needed.	Periodic replacement of detergent, water filters and air filter. Periodic replacement of printer tape if using the external printer option. Cleaning outside of the unit and basin drain screen as needed.	Identical

6. Summary of Non-Clinical Testing

Shown in **Table 3** is the new testing that was performed to demonstrate substantial equivalence of the enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System with the proposed modification. There are no proposed modifications associated with Revital-Ox 2X Enzymatic Detergent, S40 Sterilant Concentrate or MaxFlow Connectors.

Table 3. Summary of verification activities.

Test	Test Description and Acceptance Criteria	Result
Chemical Delivery	The proposed Chemical Delivery System was used in reprocessing cycles to deliver S40 Sterilant Concentrate to the processor to form the use dilution. The delivery of chemistry must be reproducible.	PASS
Material Compatibility	Tensile testing was performed on the proposed material for the Chemical Delivery System unexposed or exposed to the ingredients of S40 Sterilant Concentrate. The materials of construction of the Chemical Delivery System must be compatible with the ingredients of S40 Sterilant Concentrate as demonstrated by no change tensile testing.	PASS
Rinsing Efficacy	A representative endoscope was exposed to multiple processing cycles and extracted per ISO 10993-12. The device extracts were analyzed to verify chemical residual levels were below the highest acceptable levels.	PASS
Biocompatibility	Based on results of toxicological review per ISO 10993-1, representative endoscopes were exposed to multiple processing cycles and extracted per ISO 10993-12. The device extracts were tested for cytotoxicity per ISO 10993-5 to verify that the device extracts were non-cytotoxic.	PASS

7. 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 (K230930), Class II (21 CFR 876.1500), product code FEB.