June 30, 2023

STERIS Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K230930
Trade/Device Name: enspire 3000 Cleaning and Liquid Chemical Sterile Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: March 31, 2023
Received: April 3, 2023

Dear Anthony Piotrkowski:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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)*
K230930

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, 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.

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.

STERIS®

510(k) Summary
enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System
K230930

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600

Contact: Tony Piotrkowski
Director, Regulatory Affairs
Tel: 440-392-7437
Email: tony_piotrkowski@steris.com

Summary Date: June 30, 2023

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:	Accessories, Cleaning, for Endoscope
Classification Number:	21 CFR 876.1500
Product Code:	FEB

2. Predicate Device

EVOTECH Endoscope Cleaner and Reprocessor, K152189

Reference Device: SYSTEM 1 endo Liquid Chemical Sterilant Processing System, K210737

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 assess the integrity of the flexible endoscope throughout the process. The enspire 3000 processor maintains inflation of the processed device to reduce the risk of ingress of fluid during processing and the pressure monitoring is repeated at the end of the processing cycle. 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.

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 enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device EVOTECH Endoscope Cleaner and Reprocessor (K152189)	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 EVOTECH® ECR Endoscope Cleaner and Reprocessor, a washer/disinfector, is indicated for use with high-level disinfectant CIDEX® OPA Concentrate Solution and an enzymatic detergent (CIDEZYME XTRA) to achieve cleaning and high level disinfection of heat sensitive (>60°C) semi-critical	Similar. The enspire 3000 Processor monitors the pressure of the devices and cleans devices like the EVOTECH ECR. The enspire 3000 Processor provides liquid chemical

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device EVOTECH Endoscope Cleaner and Reprocessor (K152189)	Comparison
	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.	endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® ECR Endoscope Cleaner and Reprocessor System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)	sterilization while the EVOTECH ECR provides high level disinfection.
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 pressure • 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 two basins. • The processor lid is opened with a foot pedal. • Devices with internal lumens are interfaced with the processor using connectors, i.e. EVOTECH Connector • Instrument leak test performed at beginning and end of cycle to monitor endoscope integrity • Automatic blockage detection system • CIDEZYME XTRA Multi Enzymatic Detergent dispensed during wash phase of the processing cycle. • CIDEX OPA Concentrate High Level Disinfectant dispensed during HLD phase of the processing cycle. • Processor provides rinsing with 0.2 micron filtered water after cleaning and disinfection phases • Optional alcohol rinse at end of cycle to aid in drying.	Similar
Process Parameters	Standardized cycle parameters cannot be altered by the operator. The critical process parameters monitored during processing:	Critical process parameters monitored during processing: • Cleaning time	Similar

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device EVOTECH Endoscope Cleaner and Reprocessor (K152189)	Comparison
	• Detergent dilution and cleaning time • Detergent dilution temperature • Use dilution contact time • Use dilution temperature	• HLD contact time and temperature • MEC Monitor of CIDEX OPA concentration	
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 Pressure Monitor Test. • Alarms if loss of pressure inside of endoscope indicates a leak	• The processor monitors and controls the detergent and HLD contact times. • Cycle record documents successful cycle completion or identifies fault if cycle aborts • Alarms if loss of pressure inside of endoscope indicates a leak • Monitors HLD contact time and temperature • MEC Monitor will abort cycle if CIDEX OPA Concentrate solution does not meet preset limits	Similar
Design Features	• Unalterable and standardized Processing Cycle for cleaning and liquid chemical sterilization • Filter Pressure Monitor 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 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	• Multiple processing cycles available by turning on or off the Wash and Alcohol Flush features: o Wash, Disinfect, and Alcohol Flush o Wash and Disinfect Cycle o Disinfect and Alcohol Flush o Disinfect Only Cycle o Self-Disinfection Cycle • Automated stand-alone system with two operating reprocessing basins comprising hardware, software and consumables. • Basin lid features a rotating spray arm. • Designed to perform process using only CIDEZYME XTRA Multi Enzymatic Detergent and high level disinfection using only CIDEX OPA. • Processor provides rinsing with 0.2 micron filtered water after wash and disinfect phases • Includes Bar code scanner, employs touchscreen display interface; has	Similar. enspire 3000 Processor has one unalterable processing cycle that always includes cleaning and liquid chemical sterilization.

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device EVOTECH Endoscope Cleaner and Reprocessor (K152189)	Comparison
	• 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	USB drive for electronic cycle download • Printer integral to unit.	
Cycle Parameters			**Comparison**
Pressure Monitor Test	Performed at beginning and end of cycle	Performed at beginning and end of cycle	Same
Pre-Rinse Phase	Pre-filtered water at 40°C	0.2 micron filtered water at 35°C	Similar
Incoming Water Temp	37 - 45°C	37°C	Similar
Cleaning Phase Temperature	> 42.2°C	37°C	Similar
Cleaning Phase Exposure Time	2 minutes	Not identified	No information provided for the predicate
Rinse Phase after Cleaning	Pre-filtered water below 55°C	0.2 micron filtered water at 45°C	Similar
HLD or LCS Phase Temperature Range	LCS: 46.6 - 50°C	HLD: Minimum of 50°C	Similar
HLD or LCS Phase Exposure Time	6 minutes	Minimum of 5 minutes	Similar
Rinse Phase after HLD or LCS	Hot potable tap water that is pre-filtered then filtered through a 0.2 micron bacterial retentive filter	0.2 micron filtered water at 30°C for first rinse, then at 25°C for second rinse	Similar
Number of rinses	2 after Cleaning Phase 2 after LCS Phase	1 after Wash Phase 2 after Disinfection Phase	Similar
Alcohol Rinse	No	Yes, if selected in cycle	enspire 3000 processor does not offer alcohol flush
Air Purge	Yes	Yes	Same
Approximate Cycle Time	38 minutes	33 minutes	Similar
Accessories			**Comparison**
Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	CIDEZYME XTRA Multi Enzymatic Detergent	Both are enzymatic detergents
High Level Disinfectant	N/A	CIDEX OPA	enspire does not provide HLD.

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (CLCSPS)	Predicate Device EVOTECH Endoscope Cleaner and Reprocessor (K152189)	Comparison
Liquid Chemical Sterilant	S40 Sterilant Concentrate	N/A	EVOTECH ECR does not liquid chemically sterilize devices.
Connectors	Max Flow Connectors	EVOTECH Connectors	Similar, both provide a means to attach instruments for flow of internal lumens during processing
Chemical Indicator	Celerity Chemical Indicator for enspire 3000 Cleaning and Liquid Chemical Sterile Processing System	Integrated automated Minimum Effective Concentration (MEC) testing during cycle	Both provide means of confirming germicide reached effective concentration
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant	N/A	Spore Test Strip is not recommended or cleared for use with the predicate device.
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.	Cleaning seals, replacing solutions, replacing 0.2 micron filters, cleaning coarse screen, cleaning drip tray, printer paper replacement, cleaning fan filter	Similar

Table 2. Reference Device Comparison Table

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (LCSPS)	Reference Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K210737)	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	The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical, heat-sensitive medical devices and their accessories in healthcare facilities. The SYSTEM 1 endo Process 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 45.5 to 60°C and	Similar. The enspire Processor monitors the pressure of the device and cleans devices in addition to liquid chemical sterilization. enspire 3000 CLCSPS replaces manual cleaning of medical devices excepting duodenoscopes

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (LCSPS)	Reference Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K210737)	Comparison
	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.	rinses the load with 0.2 micron filtered water. The SYSTEM 1 endo Process uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	
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 monitor performed at beginning and end of cycle to monitor endoscope pressure • 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	• A microprocessor controlled unit with interchangeable processing trays/containers. • The processor lid opens to reveal the processing chamber in which the load is placed. • Devices with internal lumens are interfaced with the processor using connectors, i.e. Quick Connects. • S40 Sterilant is placed in a specialized compartment and when the processor fills with water, it creates the sterilant use dilution from the single use sterilant cup. • The processor monitors and controls the use dilution contact time. • The processor automatically rinses the load with 0.2 micron filtered water to remove sterilant residuals.	Similar. enspire 3000 Processor has additional pressure monitor and cleaning capabilities.
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	Standardized cycle parameters cannot be altered by the operator. The critical process parameters are: • Use dilution contact time • Use dilution temperature • Peracetic acid concentration	Similar

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (LCSPS)	Reference Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K210737)	Comparison
	• Use dilution contact time • Use dilution temperature	• Integrity of the internal water filter (tested by the system)	
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	• Cycle record documents successful cycle completion or identifies fault if cycle aborts • Alarms if thermocouples indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if conductivity probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification in Diagnostic Cycle • Alarms if pressure transducer indicates internal water filter failed integrity test.	Similar
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 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	• Microprocessor controlled unalterable and standardized Liquid Chemical Sterilization and Diagnostic Cycles • Intended for use with only S40 Sterilant Concentrate • Automated dilution and delivery of S40 Sterilant • Processor provides 0.2 micron filtered water for liquid chemical sterilization and rinsing • Make-up 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	Similar. enspire 3000 Processor has additional cleaning capabilities.

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (LCSPS)	Reference Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K210737)	Comparison
	• 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**
Pressure Monitor Test	Performed at beginning and end of cycle	N/A	Pressure monitor not available on SYSTEM 1 endo
Pre-Rinse Phase	Pre-filtered water at 40°C	N/A	Cleaning not available on SYSTEM 1 endo
Incoming Water Temp	37 - 45°C	≥ 43°C	Cleaning not available on SYSTEM 1 endo
Cleaning Phase Temperature	> 42.2°C	N/A	Cleaning not available on SYSTEM 1 endo
Cleaning Phase Exposure Time	2 minutes	N/A	Cleaning not available on SYSTEM 1 endo
Rinse Phase after Cleaning	Pre-filtered water below 55°C	N/A	Cleaning not available on SYSTEM 1 endo
LCS Phase Temperature Range	LCS: 46.6 - 50°C	46 - 55°C	Identical
LCS Phase Exposure Time	6 minutes	6 minutes	Identical
Rinse Phase after LCS Phase	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 LCS Phase	Additional rinses on enspire 3000 CLCSPS due to cleaning phase
Air Purge	Yes	Yes	Identical
Approximate Cycle Time	38 minutes	18-20 minutes	enspire has additional time for cleaning phase
Accessories			**Comparison**
Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	N/A	Cleaning not available on SYSTEM 1 endo

Feature	Proposed Device enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System (LCSPS)	Reference Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K210737)	Comparison
Liquid Chemical Sterilant	S40 Sterilant Concentrate	S40 Sterilant Concentrate	Identical
Connectors	Max Flow Connectors	Quick Connects	Similar, both provide a means to attach instruments for flow of internal lumens during processing
Chemical Indicator	Celerity Chemical Indicator for enspire 3000 Cleaning and Liquid Chemical Sterile Processing System	VERIFY Chemical Indicator for S40 Sterilant is available for use in SYSTEM 1 endo LCSPS	Both provide means of confirming sterilant reached effective concentration
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant	VERIFY Spore Test Strip for S40 Sterilant for use in SYSTEM 1 endo LCSPS	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 water filters and air filter. Periodic replacement of printer tape if using the external printer option.	Similar. Detergent not used in SYSTEM 1 endo

Table 3. S40 Sterilant Concentrate Device Comparison Table

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K211607)	Comparison
Indications for Use	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	Identical
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Germicide Exposure Time	6 minutes	6 minutes	Identical
Use Temperature	45.5-60ºC – allowable 46-55°C - typical Potency and simulated use evaluations conducted at ≤43°C	45.5-60ºC – allowable 46-55°C - typical Potency and simulated use evaluations conducted at ≤43°C	Identical
Reuse	Single use	Single use	Identical
Human Factors	Dispensed ready to use. Container is opened and diluted by the processor, thus limiting user exposure to the active ingredient	Dispensed ready to use Container is opened and diluted by the processor, thus limiting user exposure to the active ingredient	Identical
Active Ingredient	35% peroxyacetic (peracetic) acid automatically diluted for use in the SYSTEM 1E Processor.	35% peroxyacetic (peracetic) acid automatically diluted for use in the SYSTEM 1E Processor.	Identical
Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms:	It is believed that peracetic acid exerts its germicidal effect by several mechanisms:	Identical

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K211607)	Comparison
	-oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls -hydroxyl radicals produced from PAA are bactericidal -PAA damages the viral capsid and viral nucleic acid.	-oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls -hydroxyl radicals produced from PAA are bactericidal -PAA damages the viral capsid and viral nucleic acid	
Rinses	Automatic, UV-irradiated, dual 0.1 micron filtered, potable hot water.	Automatic, UV-irradiated, dual 0.1 micron filtered, potable hot water.	Identical
Microbial Efficacy			
Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Fungicidal Activity of Disinfectants AOAC Official Method 955.17	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Identical
Use Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Identical
EPA Viricidal Testing (DIS/TSS-7, Nov. 1981)	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Identical
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae* Testing conducted *in vitro*	Solution is tuberculocidal *Mycobacterium terrae* Testing conducted *in vitro*	Identical
Simulated-Use Test	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Identical
Clinical In-Use	No surviving microorganisms on representative medical devices tested	No surviving microorganisms on representative medical devices tested	Identical
Biocompatibility			

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K211607)	Comparison
Cytotoxicity Device Extracts	Two rinses with UV treated dual 0.1-micron membrane filtered water effectively reduce sterilant residues to safe levels.	Two rinses with UV treated dual 0.1-micron membrane filtered water effectively reduce sterilant residues to safe levels.	Identical
Residue Reduction	Automatic within the SYSTEM 1E Processor: Two rinses with UV treated dual 0.1-micron membrane filtered water effectively reduce sterilant residues to safe levels.	Automatic within the SYSTEM 1E Processor: Two rinses with UV treated dual 0.1-micron membrane filtered water effectively reduce sterilant residues to safe levels.	Identical
Device Material Compatibility	Compatible with medical devices as established by testing finished flexible endoscopes through 300 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Compatible with medical devices as established by testing finished flexible endoscopes through 300 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Identical

6. Summary of Non-Clinical Testing

Shown in **Table 4** is the new testing that was performed to evaluate safety and effectiveness of the enspire 3000 Cleaning and Liquid Chemical Sterilant Processing System.

Table 4. Summary of verification activities.

Test	Test Description and Acceptance Criteria	Result
Simulated Use Testing	Cleaning: Worst-case devices were soiled and processed in triplicate using the cleaning phase of the processing cycle, then examined visually and sampled for quantitation of two soil markers: protein < 6.4 µg/cm^2 and TOC < 12 µg/cm^2.	PASS
	Liquid Chemical Sterilization: Worst case devices were inoculated with *Geobacillus stearothermophilus* in triplicate trials and processed using the LCS phase of the processing cycle, then sampled to demonstrate no growth of organisms.	PASS
	Liquid Chemical Sterilization of Duodenoscopes: Worst case devices were inoculated with *Geobacillus stearothermophilus* in triplicate trials and processed using an abbreviated LCS phase of the processing cycle (2.5-minute), then sampled to demonstrate no growth of organisms.	PASS
In Use Testing	Cleaning: Clinically used devices were placed into the enspire 3000 processor and exposed to a full processing cycle. At the end of the cycle, the devices were examined visually and sampled for quantitation of two soil markers: protein < 6.4 µg/cm^2 and TOC < 12 µg/cm^2.	PASS

Test	Test Description and Acceptance Criteria	Result
	Liquid Chemical Sterilization: Clinically used devices were placed into the enspire 3000 processor and exposed to a full processing cycle. At the end of the cycle, the devices were sampled to demonstrate no growth of organisms.	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
Material Compatibility	Representative devices were exposed to multiple processing cycles and evaluated for physical changes to demonstrate material compatibility with the process and chemistries used.	PASS
Effects of Detergent on S40	Demonstrates that residual Revital-Ox detergent does not impact the concentration or pH of the S40 use dilution during a cycle	PASS
Thermometric Testing	Thermocouples placed throughout basin, sump and processed instruments to demonstrate cycle temperature is maintained at required values.	PASS
Human Factors	Typical users were capable of following written instructions for use to correctly load devices into the enspire 3000 processor, attach Max Flow Connectors, insert sterilant and accessories, and successfully run the processing cycle. In addition, Service Technicians were capable of following installation and maintenance instructions for the enspire 3000 processor.	PASS
Electrical Safety Conformance	Meets requirements per: • UL 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements, 3rd Edition • IEC 61010-2-040:2020, 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 • IEC 60601-1-2, Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements	PASS
Software Validation	Meets requirements per: • IEC 62304:2006/A1:2016, Medical device software – Software life cycle processes [Including Amendment 1(2016)]	PASS

Clinical testing: Not applicable.

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 (K152189), Class II (21 CFR 876.1500), product code FEB.