October 3, 2023

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

Re: K232918
Trade/Device Name: enspire 300 Series Automated Endoscope Reprocessor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NZA
Dated: September 19, 2023
Received: September 19, 2023

Dear Nalepka Jennifer:

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.

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232918

Device Name

enspire 300 Series Automated Endoscope Reprocessor

Indications for Use *(Describe)*

The enspire™ 300 Series Automated Endoscope Reprocessor System is intended to effectively provide a pressure and channel monitor, clean, high-level disinfect, rinse and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes. The validated cleaning process replaces manual cleaning for endoscopes other than duodenoscopes. Manual Cleaning of endoscopes is required prior to placement in high level disinfection only cycle.

The enspire 300 Series Automated Endoscope Reprocessor System uses Revital-Ox PAA High Level Disinfectant to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices. It automatically mixes the Part A and Part B solutions, high level disinfects the load during a controlled cycle and rinses the load. The wash phase of the enspire 300 Series Automated Endoscope Reprocessor System cycle uses only Revital-Ox 2X Concentrate Enzymatic Detergent to perform cleaning.

The Revital-Ox PA High Level Disinfectant (HLD) is a two-part solution, which when mixed, is intended to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes, when used in the enspire 300 AER.

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 K232918
enspire 300 Series Automated Endoscope Reprocessor

STERIS Corporation
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Phone: (440) 354-2600

Contact: Jennifer Nalepka
Manager, Regulatory Affairs
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Summary Date: October 2, 2023

1. Device Name

Trade Name:	enspire 300 Series Automated Endoscope Reprocessor
Device Classification:	Class II
Common/usual Name:	Endoscope Cleaner and Reprocessor
Classification Name:	Accessories, Germicide, Cleaning, For Endoscopes
Classification Number:	21 CFR 876.1500
Product Code:	NZA

2. Predicate Device

enspire 300 Series Automated Endoscope Reprocessor, K230560

3. Description of Device

The enspire 300™ Series Automated Endoscope Reprocessor (AER) is a medical device processing system used for cleaning and high level disinfection of immersible, reusable, semi-critical, heat-sensitive devices such as flexible endoscopes and their accessories. The system consists of the enspire 300 AER, Revital-Ox 2X Concentrate Enzymatic Detergent (R2X), and Revital-Ox Peracetic Acid High Level Disinfectant.

The enspire 300 series AER is an automated, self-contained device for the effective cleaning and high level disinfection of semi-critical medical devices and their accessories. Prior to placement in the processor, users will be instructed to perform bedside (point of use) cleaning and manual leak testing. The devices will not require manual pre-cleaning prior to processing, with the exception of duodenoscopes which will still require manual cleaning per the manufacturer's written instructions. Channel Connectors, as identified in STERIS labeling, are used to facilitate the delivery of the R2X detergent, HLD solution and rinse water to internal channels of devices that have them.

On the first process of an endoscope, the user must create a scope profile for the endoscope in the AER. The creation of the scope profile saves key endoscope attributes to the AER which are used to monitor the cycle during processing of the device. Once the device is positioned in the enspire 300 AER and optional operator ID, case ID, procedure ID and physician information is inputted, the operator initiates the processing cycle during which the Processor will create and maintain the conditions necessary for effective cleaning and high level disinfection. At the beginning of the processing cycle, an automated pressure monitor is performed to confirm the integrity of the flexible endoscope. In parallel with the pressure monitor and prior to initiation of the cleaning phase, the processing system will evaluate the flow coefficient of each individual channel and compare to their respective reference value stored in the device profile created prior to first processing. The enspire 300 AER maintains inflation of the processed device throughout the process to prevent ingress of fluid in the event of any loss of integrity. At the end of the processing cycle, the cleaned and high level disinfected devices are rinsed with 0.2 micron filtered potable water followed by a dried, oil free, filtered compressed air purge to evacuate rinse water from the endoscope channels. The AER, which is micro-processor controlled and continually monitored, provides documentation of each cycle.

The enspire 300 AER utilizes Revital-Ox 2X Concentrate Enzymatic Detergent for cleaning and Revital-Ox Peracetic Acid High Level Disinfectant for high level disinfection. Revital-Ox PAA HLD is a two part solution consisting of Part A, 15% PAA, and Part B, conditioner.

4. Indications for Use

The enspire 300 Automated Endoscope Reprocessor is intended to effectively provide a pressure and channel monitor, clean, high-level disinfect, rinse and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes. The validated cleaning process replaces manual cleaning for endoscopes other than duodenoscopes. Manual Cleaning of endoscopes is required prior to placement in high level disinfection only cycle.

The enspire 300 Automated Endoscope Reprocessor uses Revital-Ox PA High Level Disinfectant to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices. It automatically mixes the Part A and Part B solutions; high level disinfects the load during a controlled cycle and rinses the load. The wash phase of the enspire 300 Series Automated Endoscope Reprocessor cycle uses only Revital-Ox 2X Concentrate Enzymatic Detergent to perform cleaning.

The Revital-Ox PA High Level Disinfectant (HLD) is a two-part solution, which when mixed, is intended to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes, when used in the enspire 300 AER.

5. Technological Characteristic Comparison Tables

Table 1. Predicate Device Comparison Table

Feature	Proposed enspire 300 Series AER	Predicate enspire 300 Series AER (K230560)	Comparison
Indications for Use	The enspire 300 Automated Endoscope Reprocessor is intended to effectively provide a pressure and channel monitor, clean, high-level disinfect, rinse and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes. The validated cleaning process replaces manual cleaning for endoscopes other than duodenoscopes.	The enspire 300 Automated Endoscope Reprocessor is intended to effectively provide a pressure and channel monitor, clean, high-level disinfect, rinse and air purge validated immersible, reusable, semi-critical, heat sensitive medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes. The validated cleaning process replaces manual cleaning for endoscopes other than duodenoscopes.	Identical

Feature	Proposed enspire 300 Series AER	Predicate enspire 300 Series AER (K230560)	Comparison
	Manual Cleaning of endoscopes is required prior to placement in high level disinfection only cycle. The enspire 300 Automated Endoscope Reprocessor uses Revital-Ox PA High Level Disinfectant to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices. It automatically mixes the Part A and Part B solutions; high level disinfects the load during a controlled cycle and rinses the load. The wash phase of the enspire 300 Series Automated Endoscope Reprocessor cycle uses only Revital-Ox 2X Concentrate Enzymatic Detergent to perform cleaning.	Manual Cleaning of endoscopes is required prior to placement in high level disinfection only cycle. The enspire 300 Automated Endoscope Reprocessor uses Revital-Ox PA High Level Disinfectant to provide high level disinfection of validated immersible, reusable, semi-critical, heat sensitive medical devices. It automatically mixes the Part A and Part B solutions; high level disinfects the load during a controlled cycle and rinses the load. The wash phase of the enspire 300 Series Automated Endoscope Reprocessor cycle uses only Revital-Ox 2X Concentrate Enzymatic Detergent to perform cleaning.	
Operating Principles / Technology	The enspire 300 AER provide delivery of solutions and fluids to endoscopes and their accessories. Revital-Ox 2X Concentrate Enzymatic detergent and Revital-Ox PAA HLD are introduced into the enspire 300 AER to provide cleaning and high level disinfection. Decontamination cycle is used to help with routine maintenance and to help prevent contamination of the Reprocessor during period of inactivity. Descaling Cycle is used to help prevent and remove scale build-up in the Reprocessor.	The enspire 300 AER provide delivery of solutions and fluids to endoscopes and their accessories. Revital-Ox 2X Concentrate Enzymatic detergent and Revital-Ox PAA HLD are introduced into the enspire 300 AER to provide cleaning and high level disinfection. Decontamination cycle is used to help with routine maintenance and to help prevent contamination of the Reprocessor during period of inactivity. Descaling Cycle is used to help prevent and remove scale build-up in the Reprocessor.	Identical
Process Parameters	The cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temp • Water Volume • Chemical Volume	The cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temp • Water Volume • Chemical Volume	Identical

Feature	Proposed enspire 300 Series AER	Predicate enspire 300 Series AER (K230560)	Comparison
	• Channel irrigation flow/pressure	• Channel irrigation flow/pressure	
Process Monitors	Channel irrigation flow alarms when endoscope channel is obstructed or disconnected, if pressure too low or too high, or if sensor defect is detected. Chemical volume alarms if chemical injected volume is too high, too low, chemical pump is defective or chemical container has inadequate volume to complete the cycle. Water volume alarms when water level is too high for HLD. Temperature alarm is triggered when temperature is too high, sump takes too long to heat, RTD variance exceeded or a sensor is defective. Alarm is triggered if Real Time Clock error is detected.	Channel irrigation flow alarms when endoscope channel is obstructed or disconnected, if pressure too low or too high, or if sensor defect is detected. Chemical volume alarms if chemical injected volume is too high, too low, chemical pump is defective or chemical container has inadequate volume to complete the cycle. Water volume alarms when water level is too high for HLD. Temperature alarm is triggered when temperature is too high, sump takes too long to heat, RTD variance exceeded or a sensor is defective. Alarm is triggered if Real Time Clock error is detected.	Identical
Design Features	• Intended for use with Revital-Ox 2X Concentrate Enzymatic Detergent and Revital-Ox PAA HLD • Microprocessor controlled • Internal components constructed of stainless steel, silicone, polypropylene and PVDF. • Processor provides pre-filtered water and the proposed filters have a new support material. • 0.2 micron filtered water used for rinsing • Automated injection of cleaning and HLD solutions, with accuracy monitored by a flow meter • Uses dried, oil free and filtered compressed air for Air Purge • Automated endoscope Pressure monitor • Monitors channel flow	• Intended for use with Revital-Ox 2X Concentrate Enzymatic Detergent and Revital-Ox PAA HLD • Microprocessor controlled • Internal components constructed of stainless steel, silicone, polypropylene and PVDF. • Processor provides pre-filtered water • 0.2 micron filtered water used for rinsing • Automated injection of cleaning and HLD solutions, with accuracy monitored by a flow meter • Uses dried, oil free and filtered compressed air for Air Purge • Automated endoscope Pressure monitor • Monitors channel flow • Includes a bar code scanner; employs touchscreen display interface	Similar – function and biocompatibility of pre-filter is unchanged.

Feature	Proposed enspire 300 Series AER	Predicate enspire 300 Series AER (K230560)	Comparison
	• Includes a bar code scanner; employs touchscreen display interface • Separate, optional printer	• Separate, optional printer	
Cycle Parameters			**Comparison**
Pressure Monitor	Performed at the beginning of the cycle	Performed at the beginning of the cycle	Identical
Flow check	Performed at the beginning and end of the cycle	Performed at the beginning and end of the cycle	Identical
Cleaning Phase Temperature	50-55°C	50-55°C	Identical
Cleaning Phase Exposure time	4.5 minutes wash	4.5 minutes wash	Identical
Rinse phase after cleaning	30 seconds	30 seconds	Identical
HLD phase Temperature	50-55°C	50-55°C	Identical
HLD phase exposure time	3 minutes	3 minutes	Identical
Rinse Phase after HLD phase	30 seconds	30 seconds	Identical
Number of rinses	2	2	Identical
Air purge	Performed between each phase and at the end of the cycle	Performed between each phase and at the end of the cycle	Identical
Accessories			**Comparison**
Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	Identical
HLD	Revital-Ox PAA HLD	Revital-Ox PAA HLD	Identical
Chemical Indicator	enspire 300 series AER Process monitor. Peracetic acid dose indicator for routine monitoring of enspire 300 AER using Revital-Ox PAA HLD. Chemical reaction on indicator pad to produce color change.	enspire 300 series AER Process monitor. Peracetic acid dose indicator for routine monitoring of enspire 300 AER using Revital-Ox PAA HLD. Chemical reaction on indicator pad to produce color change.	Identical
Scope Connectors / Flow Units	Scope connectors are required for all lumens of endoscopes.	Scope connectors are required for all lumens of endoscopes.	Identical
Operator Maintenance	Periodic replacement of water filters. Periodic replacement of printer tape if using the external printer option. Running the decontamination cycle every 24 hours.	Periodic replacement of water filters. Periodic replacement of printer tape if using the external printer option. Running the decontamination cycle every 24 hours.	Identical

6. Summary of Non-Clinical Testing

Shown in **Table 2** is the new testing that was performed to evaluate the modified device.

Table 2. Summary of verification activities.

Test	Acceptance Criteria	Result
Performance testing with replacement pre-filters	The modification does not affect the performance of the device.	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 (K230560), Class II (21 CFR 876.1500), product code NZA.