July 21, 2023

STERIS Corporation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K230560
Trade/Device Name: enspire 300 Series Automated Endoscope Reprocessor System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NZA
Dated: June 13, 2023
Received: June 13, 2023

Dear Gregory Land:

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
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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.

510(k) Number *(if known)*
K230560

Device Name
enspire 300 Series Automated Endoscope Reprocessor System

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.

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510(k) Summary
enspire 300 Series Automated Endoscope Reprocessor System

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

Contact: Gregory Land
Lead Regulatory Affairs Specialist
Tel: 440-392-7424

Summary Date: July 20, 2023

510(k) Number: K230560

1. Device Name

Trade Name:	enspire 300 Series Automated Endoscope Reprocessor System
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

Reliance Advance Endoscope Processing System, K123768

3. Description of Device

The enspire 300™ Series Automated Endoscope Reprocessor System (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 (HLD).

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 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 assess 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 reduce the risk of 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 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 Automated Endoscope Reprocessor System 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 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.

5. Technological Characteristic Comparison Tables

Table 1. Predicate Device Comparison Table

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
Indications for Use	The enspire 300 Automated Endoscope Reprocessor System is intended to effectively provide a pressure	Cleaning and high level disinfection of up to two immersible, reusable, heat-sensitive, semi-	Similar – both systems provide cleaning and high-level

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
	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 System 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 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	critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. During the system's standardized Endoscope Processing Cycle, cleaning is achieved within the Cleaning phase, and high level disinfection is achieved within the 50 – 57°C HLD phase (4 minute generation sequence followed by a 6-minute exposure sequence). Manual cleaning is not required prior to processing in Reliance EPS version 2.	disinfection

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
	medical devices including, but not limited to, flexible endoscopes and non-channeled naso-endoscopes, when used in the enspire 300 AER.		
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 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 cleaning and high level disinfection. Decontamination cycles (D-Long with CIP-200 and D-Short) are used to prevent biofilm formation in the Reliance EPS Processor and ensure effective processing following periods of processor inactivity	Similar – the subject device and the predicate device both use enzymatic cleaner and peracetic acid for cleaning and high level disinfection, respectively. The disinfection differs between the two, the subject device uses thermal disinfection while the predicate uses chemical.
Process Parameters	The cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temp • Water Volume • Chemical Volume • Channel irrigation flow/pressure	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temp • Cleaning solution and Reliance DG concentration • Water filter integrity	Similar- the subject device uses water and chemical volume rather than solution concentration. The subject device also provides flow monitoring
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	Control Handle Boot pressure alarms if pressure too low to process, or if too high and could potentially damage scopes (specification 6.5 to 10.5 PSI).	Similar – the proposed device has additional process monitoring of all endoscope lumens

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
	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.	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.	individually.
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 0.2 micron filtered water 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 • Separate, optional printer	• 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 • Automated injection of solutions with accuracy monitored by a flow meter. • Automated generation and delivery of high level disinfectant solution • Air intake for Air Purge is HEPA filtered • Automated endoscope leak test • Barcode scanner • Separate, optional printer	Similar – the subject device has additional monitoring of channel flow and use of a touch screen.
Cycle Parameters			Comparison
Pressure Monitor	Performed at the beginning of the cycle	Performed at the beginning of the cycle	Same
Flow check	Performed at the beginning and end of the cycle	Not present	Different – The subject device has a Flow

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
			Check in the cycle which monitors the flow to each lumen of an endoscope
Cleaning Phase Temperature	50-55°C	50-57°C	Similar – subject device operates in a narrower range of the predicate
Cleaning Phase Exposure time	4.5 minutes wash	5 minutes	Similar – subject device is quicker
Rinse phase after cleaning	30 seconds	40 seconds	Similar – subject device is quicker
HLD phase Temperature	50-55°C	50-57°C	Similar – subject device operates in a narrower range of the predicate range
HLD phase exposure time	3 minutes	6 minutes	Similar – subject device is quicker
Rinse Phase after HLD phase	30 seconds	40 seconds	Similar – subject device is quicker
Number of rinses	2	2	Same
Air purge	Performed between each phase and at the end of the cycle	Performed at the end of the cycle	Same
Accessories			Comparison
Detergent	Revital-Ox 2X Concentrate Enzymatic Detergent	Klenzyme	Similar – both are enzymatic cleaners
HLD	Revital-Ox PAA HLD	Reliance DG	Similar – both are peracetic acid based HLD
Chemical Indicator	enspire 300 series AER Process monitor. Peracetic acid dose indicator for routine monitoring of enspire 300 AER using Revital-Ox PAA	VERIFY Process Indicator for Reliance EPS. Peracetic acid dose indicator for routine monitoring of Reliance	Similar – both use a chemical indicator but the indicator is different.

Feature	Proposed enspire 300 Series AER	Predicate K123768 Reliance Advanced EPS	Comparison
	HLD. Chemical reaction on indicator pad to produce color change.	EPS using Reliance DG. Chemical reaction on indicator pad to produce color change.	
Scope Connectors / Flow Units	Scope connectors are required for all lumens of endoscopes.	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.	Similar – both use connectors to flush lumens of endoscopes
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 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.	Similar – both require the periodic replacement of filters and running of decontamination cycles.

Table 2. HLD Device Comparison Table

Feature	Proposed Revital-Ox PAA HLD	Predicate Reliance DG Dry Germicide	Comparison
Intended Use	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.	The Reliance Endoscope Processing System is intended for washing and high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50-57°C HLD phase of the endoscope processing cycle (4-minute generation sequence followed by a 6-minute exposure sequence).	Same
Germicidal	High level disinfectant	High level disinfectant	Same

Feature	Proposed Revital-Ox PAA HLD	Predicate Reliance DG Dry Germicide	Comparison
claim			
Germicide Exposure time for HLD (min)	3 minutes	10 minutes (4-minute generation sequence followed by a 6-minute exposure sequence)	Similar – The exposure time for high level disinfection is quicker on the subject device
Use Temperature	50-55°C	50-57°C	Similar – the operating range is narrower and included in the predicate device
Reuse	Single Use dilution	Single Use dilution	Same
Active Ingredient	Peracetic acid	Peracetic acid	Same
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]	Same
Rinse	2 rinses, 30 seconds each with 0.2µ filtered water	2 rinses, 40 seconds each, with 0.2µ filtered water	Similar – the rinse time of the subject device is quicker
Microbial Efficacy			
Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes*	Meets efficacy requirements. *Bacillus subtilis* *Clostridium sporogenes*	Same
Confirmatory Sporicidal Activity of Disinfectants	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogene*	Meets efficacy requirements.[5] *Bacillus subtilis* *Clostridium sporogenes*	Same

Feature	Proposed Revital-Ox PAA HLD	Predicate Reliance DG Dry Germicide	Comparison
AOAC Official Method 966.04			
Fungicidal Activity of Disinfectants AOAC Official Method 955.17	Solution is fungicidal. *Trichophyton interdigitale*	Solution is fungicidal. *Trichophyton mentagrophytes*	Same
Use-Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal *Salmonella enterica* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Same
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*	Same
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae*	Solution is tuberculocidal *Mycobacterium terrae*	Same
Simulated Use Test	Meets efficacy requirement. ≥ 6 log reduction *Mycobacterium terrae* in a manual application	Meets efficacy requirement. ≥ 6 log reduction *Mycobacterium terrae* in a manual application	Same
Clinical In-use test	Non surviving microorganisms on representative medical devices tested	Non surviving microorganisms on representative medical devices tested	Same
Bio compatibility			
Cytotoxicity device extracts	Non-Cytotoxic per ISO 10993-5	Non-cytotoxic per ISO 10993-5	Same
Residue Reduction	Automatic within the enspire 300 AER. 2 rinses with 0.2µ filtered water after HLD cycle effectively reduces	Automatic within the Reliance Endoscope Processor, 2 rinses with 0.2µ filtered water after	Same

Feature	Proposed Revital-Ox PAA HLD	Predicate Reliance DG Dry Germicide	Comparison
	germicide residues to safe levels.	HLD cycle effectively reduces residues germicide residues to safe levels.	
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 or rigid devices. Some materials show cosmetic changes such as fading 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 fading of black anodized aluminum without harm to the base material.	Same

6. Summary of Non-Clinical Testing

Shown in **Table 3** is the new testing that was performed to evaluate the enspire 300 Automated Endoscope Reprocessor System.

Table 3. Summary of verification activities.

Test	Acceptance Criteria	Result
Simulated Use Testing	Cleaning: Worst-case devices were soiled and processed in triplicate trials 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
	High Level Disinfection: Worst case devices were inoculated with *Mycobacterium. terrae* in triplicate trials and processed using the HLD phase of the processing cycle, then sampled to demonstrate ≥6 $\log_{10}$ reduction per channel of *M. terrae.*	PASS
In Use Testing	Cleaning: Clinically used devices were placed into the enspire 300 AER 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
	High Level Disinfection: Clinically used devices were placed into the enspire 300 AER 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 (Cytotoxicity	A representative endoscope was exposed to multiple processing cycles and extracted per ISO 10993-12:2021. The device extracts	PASS

Test	Acceptance Criteria	Result
test)	were analyzed to verify chemical residual levels were below the highest acceptable levels.	
Biocompatibility	A representative endoscope was exposed to multiple processing cycles and extracted per ISO 10993-12: 2021. The device extracts were tested for • Hemolysis per ISO 10993-4:2017 • Cytotoxicity per ISO 10993-5:2009/(R) 2014 • Sensitization per ISO 10993-10:2021 • Acute Systemic toxicity per ISO 10993-11:2017 • Irritation per ISO 10993-23:2021	PASS
Toxicological Assessment	The Toxicity assessment of the cleaning and HLD Chemistries for short-term endpoints and the long term/repeated exposure should show no significant risk concerns.	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
Human Factors	Typical users were capable of following written instructions for use to correctly load devices into the enspire 300 AER, attach Scope Connectors, and successfully run the processing cycle. .	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 60601-1-2:2015, +A1:2021 Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.	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 required for the subject device

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 (K123768), Class II (21 CFR 876.1500), product code NZA.