March 2, 2018

Steris Corporation
Marcia Benedict
Senior Director, Regulatory Affairs
5976 Heisley Rd
Mentor, Ohio 44060

Re: K173256
Trade/Device Name: System 1 endo Liquid Chemical Sterilant Processing System
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: Class II
Product Code: MED
Dated: January 31, 2018
Received: February 1, 2018

Dear Marcia Benedict:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173256

Device Name

SYSTEM 1 endo Liquid Chemical Sterilant Processing System

Indications for Use *(Describe)*

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 Processor 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 rinses the load with 0.2 micron filtered water.

The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For
SYSTEM 1 endo
Liquid Chemical Sterilant Processing System

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Submission Date: February 26, 2018

Premarket Notification Number: **K173256**

1. Device Name

Trade Name:	**SYSTEM 1 endo Liquid Chemical Sterilant Processing System**
Device Class:	Class 2
Common/usual Name:	Liquid Chemical Sterilizer
Classification Name:	Sterilant, Medical devices, Liquid Chemical Sterilants/Disinfectants
Classification Number:	21 CFR 880.6885
Product Code:	MED

2. Predicate Device

The claimed primary predicate device is the SYSTEM 1E Liquid Chemical Sterilant Processing System, cleared most recently under K170956.

The S1E prior clearances include Premarket submissions K090036, K101409, K102462, K110352, K131078, K161683.

3. Description of Device

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is a liquid chemical sterilization system, utilizing peracetic acid to process totally immersible semi-critical heat-sensitive medical devices and their accessories. The system consists of the SYSTEM 1 endo Processor and S40 Sterilant Concentrate, interchangeable Processing Trays/Containers, and Quick Connects.

This new liquid chemical sterilant processing system is based substantially on the predicate device, which was most recently cleared via K170956.

The SYSTEM 1 endo Processor is an automated, self-contained device that uses S40 Sterilant Concentrate to create and maintain the conditions necessary for liquid chemical sterilization in 6 minutes. Following processing, the liquid chemically sterilized articles are rinsed with 0.2 micron filtered potable water and are ready for use or may be prepared for storage. The processor, which is computer controlled and continually monitored, provides printed documentation of each cycle. The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate. Upon loading the single-use cup, the active ingredient in S40 – peracetic acid – is combined with inert ingredients (builders) to form a use dilution which inhibits corrosion of metals, polymers and other materials.

The interchangeable processing trays/containers are made to accommodate a variety of semi-critical instrument types and models. Each container is designed to maintain instruments in position while specific SYSTEM 1 endo Quick Connects, if required, facilitate delivery of the sterilant use-solution and rinse water to internal channels. **Table 1** compares the proposed and predicate devices.

4. Intended Use

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 Processor 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 rinses the load with 0.2 micron filtered water.

The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.

5. Description of Technological Similarities and Differences

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is the same as the predicate device except for the specific differences described in this submission. The differences between the proposed and predicate devices, identified in **Table 1** and **2** below, include use of a 0.2 micron bacterial retentive water filter in place of the predicate's extensive water treatment process. Appropriate changes are made to software and labeling as a result. These differences raise no new concerns of safety and effectiveness when compared to the predicate device.

Table 1. Processor Comparison Table

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
Intended Use **Indications for Use**	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 Processor 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 rinses the load with 0.2	The SYSTEM 1E Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable critical and semi-critical heat-sensitive medical devices in healthcare facilities. The SYSTEM 1E Processor 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 rinses the load with extensively	The S1 endo LCSPS's intended use is limited to semi-critical medical devices and their accessories.

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
	micron filtered water. The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	treated* potable water. After completion of a cycle, critical devices should be used immediately; semi-critical devices should be used immediately or may be handled and stored in a manner similar to that of high level disinfected endoscopes. Critical devices not used immediately should be processed again before use. The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices. * The extensive treatment of EPA potable water consists of: 1. Pre-filtration through two pre-filters: • Pre-filter 1 is a gross depth filter that removes approximately 5 micron or larger particles/contaminants. • Pre-filter 2 is a surface filter that removes particles/contaminants > 0.1 micron. 2. UV Irradiation: • During transit through the UV water treatment chamber, a UV dose sufficient to achieve a $\geq$ 6-log reduction of MS2 virus is delivered to the water. 3. 0.1 micron filtration: • The water prepared by pre-filtration and UV irradiation is filtered through redundant, 0.1-micron (absolute rated) membranes to remove bacteria, fungi and protozoa > 0.1 micron.	

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
Operating Principles / Technology	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 temperature and contact time. The processor automatically rinses the load with 0.2 micron filtered water to remove sterilant residuals.	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 temperature and contact time. The processor automatically rinses the load with extensively treated filtered water to remove sterilant residuals.	Identical, except that the proposed device uses 0.2 micron filtered water in place of extensively treated water.
Process Parameters	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Use dilution contact time • Use dilution temperature • Peracetic acid concentration • Integrity of the internal water filter (tested by the system)	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Use dilution contact time • Use dilution temperature • Peracetic acid concentration • Integrity of the internal water filter (tested by the system)	Identical
Process Monitors:	• Cycle Printout 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	• Cycle Printout 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	Identical, except there is no UV system intensity to be monitored in the proposed device.

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
	• 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	• 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 • Alarms if UV monitor indicates UV intensity out of specification	
Design Features	• Microprocessor controlled unalterable and standardized liquid chemical sterilization and Diagnostic cycles • Intended for use only with 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 sequences is filtered through a 0.2 micron membrane air filter	• Microprocessor controlled unalterable and standardized liquid chemical sterilization and Diagnostic cycles • Intended for use only with S40 Sterilant Concentrate • Automated dilution and delivery of S40 Sterilant • Processor provides extensively treated (UV irradiated, 0.1 micron filtered) water for liquid chemical sterilization and rinsing • Make-up air for processor during drain sequences is filtered through a 0.2 micron membrane air filter	Identical, except that the proposed device uses 0.2 micron filtered water in place of extensively treated water.
Cycle Parameters			**Comparison**
Incoming water temp.	$\geq$ 43°C	$\geq$ 43°C	Identical
Temperature to start sterilant exposure	$\geq$ 46°C	$\geq$ 46°C	Identical
Temperature alarm point during LCS exposure	< 45.5 or > 60°C	< 45.5 or > 60°C	Identical
Temperature range of typical LCS cycle	46 - 55°C	46 - 55°C	Identical
Exposure Time – S40 use dilution	6 minutes	6 minutes	Identical

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
Rinse water preparation	Hot potable tap water • is pre-filtered • is filtered through 0.2 micron bacterial retentive membrane filter	Hot potable tap water • is pre-filtered • flows through a UV light water treatment chamber to achieve ≥ a 6-log reduction of virus • is filtered through redundant 0.1 micron membranes	The proposed device uses 0.2 micron filtered water in place of extensively treated water.
Number of rinses	2	2	Identical
Air Purge	Aids in removing excess water from instrument lumens after rinsing	Aids in removing excess water from instrument lumens after rinsing	Identical
Internal Water Filter Integrity Test	Conducted during the Diagnostic cycle	Conducted at the end of every Liquid Chemical Sterilization cycle and during the Diagnostic cycle	Only in Diagnostic Cycle of S1 endo LCSPS
Approximate Cycle Time	18 - 20 minutes	23 - 25 minutes	S1 endo has shorter total cycle time
Diagnostic Cycle	Performs 14 tests on processor's systems confirming proper function. Recommended to perform each day of use. After a failed Diagnostic cycle, a liquid chemical sterilization cycle cannot be performed until the problem is rectified and a successful Diagnostic cycle has been completed.	Performs 15 tests on processor's systems confirming proper function. Recommended to perform each day of use. After a failed Diagnostic cycle, a liquid chemical sterilization cycle cannot be performed until the problem is rectified and a successful Diagnostic cycle has been completed.	Identical except that proposed S1 endo LCSPS has no UV unit test
Accessories			**Comparison**
Sterilant	Uses S40 Sterilant Concentrate – see **Table 2**	Uses S40 Sterilant Concentrate – see **Table 2**	Identical
Processing Trays and Containers	Uses interchangeable processing trays/containers • Universal Flex Processing Tray • General Processing Container & Tray • Directed Flow Processing Container & Tray • Flexible Endoscope Processing Container & Tray	Uses interchangeable processing trays/containers • Universal Flex Processing Tray • General Processing Container & Tray • Directed Flow Processing Container & Tray • Flexible Endoscope Processing Container & Tray	Identical

Feature	Proposed Device SYSTEM 1 endo Processor (K173256)	Predicate Device SYSTEM 1E Processor (K170956)	Comparison
	• Ultrasound Processing Tray	• Ultrasound Processing Tray	
Quick Connects	Uses Quick Connects to attach instrument lumens to the Tray/Container ports	Uses Quick Connects to attach instrument lumens to the Tray/Container ports	Identical
Chemical Indicator	VERIFY Chemical Indicator is available for use in SYSTEM 1 endo LCSPS (separate clearance)	VERIFY Chemical Indicator is available for SYSTEM 1E (K102217)	Identical design
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant for use in SYSTEM 1 endo LCSPS (separate clearance)	VERIFY Spore Test Strip for S40 Sterilant (DEN110002)	Identical design
Operator Maintenance	Periodic replacement of printer tape, water filters and air filter	Periodic replacement of printer tape, water filters and air filter	Identical

Table 2. S40 Sterilant Concentrate Comparison Table

Feature	S40 Sterilant Concentrate in S1 endo LCSPS (K173256)	S40 Sterilant Concentrate in S1E LCSPS (K170956)	Comparison
Intended Use	For use in S1E and S1 endo	For use in S1E only	Adds a new intended use
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Exposure Time	6 minutes	6 minutes	Identical
Use Temperature	45.5 - 60ºC – allowable range Potency and simulated use evaluations conducted at $\leq$ 43°C	45.5 - 60ºC – allowable range Potency and simulated use evaluations conducted at $\leq$ 43°C	Identical
Reuse	Single use	Single use	Identical
Human Factors	Ready to use. Container is opened and diluted by the processor, limiting user exposure to the sterilant concentrate	Ready to use. Container is opened and diluted by the processor, limiting user exposure to the sterilant concentrate	Identical
Active Ingredient	35% peroxyacetic (peracetic) acid automatically diluted for use in the Processor	35% peroxyacetic (peracetic) acid automatically diluted for use in the Processor	Identical

Feature	S40 Sterilant Concentrate in S1 endo LCSPS (K173256)	S40 Sterilant Concentrate in S1E LCSPS (K170956)	Comparison
Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls [1] -hydroxyl radicals produced from PAA are bactericidal [2] -PAA damages the viral capsid and viral nucleic acid[3,4]	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls[1] -hydroxyl radicals produced from PAA are bactericidal[2] -PAA damages the viral capsid and viral nucleic acid[3.4]	Identical
Rinses	2 equivalent automated rinses with pre-filtered, dual 0.2 micron membrane filtered, potable hot water	2 equivalent automated rinses with pre-filtered, UV irradiated, dual 0.1 micron membrane filtered, potable hot water	Identical
Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[5] *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	Solution is bactericidal *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Solution is bactericidal *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Identical

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

Feature	S40 Sterilant Concentrate in S1 endo LCSPS (K173256)	S40 Sterilant Concentrate in S1E LCSPS (K170956)	Comparison
955.14, 955.15, 964.02	Testing conducted *in vitro*	Testing conducted *in vitro*	
EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	Solution is virucidal Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Solution is virucidal Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Identical
Tuberculocidal Activity of Disinfectants AOAC Official Method 965.12	Not performed; a quantitative suspension Tuberculocidal test was conducted	Not performed; a quantitative suspension Tuberculocidal test was conducted	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	Meets efficacy requirement. $\geq$ 6 $\log^{10}$ reduction *Geobacillus stearothermophilus* spores in a manual application.	Meets efficacy requirement. $\geq$ 6 $\log^{10}$ reduction *Geobacillus stearothermophilus* spores in a manual application.	Identical
Clinical In Use	No surviving microorganisms on representative medical devices tested in S1 endo LCSPS	No surviving microorganisms on representative medical devices tested in S1E LCSPS	Identical
Cytotoxicity Device Extracts	Two Processor controlled rinses (time, temperature, and volume equivalent to predicate) with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to non-cytotoxic levels.	Two Processor controlled rinses with pre-filtered, UV treated, dual 0.1 micron membrane filtered potable water effectively reduce sterilant residues to non-cytotoxic levels.	Identical
Residue Reduction	Two Processor controlled rinses (time, temperature, and volume equivalent to predicate) with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to safe levels.	Two Processor controlled rinses with pre-filtered, UV irradiated, dual 0.1 micron membrane filtered potable water effectively reduce sterilant residues to safe levels.	Identical

Feature	S40 Sterilant Concentrate in S1 endo LCSPS (K173256)	S40 Sterilant Concentrate in S1E LCSPS (K170956)	Comparison
Material Compatibility	Compatible with medical devices as established by testing finished medical devices through 300 cycles. No functional changes occurred to devices. Some materials show cosmetic changes such as fading of external markings (yet all remained legible) and bleaching of black anodized aluminum without harm to the base material.	Compatible with medical devices as established by testing finished medical devices through 300 cycles. No functional changes occurred to devices. Some materials show cosmetic changes such as fading of external markings (yet all remained legible) and bleaching of black anodized aluminum without harm to the base material.	Identical

6. Description of Safety and Substantial Equivalence

The SYSTEM endo Liquid Chemical Sterilant Processing System is the same as the predicate device except for the specific differences described in this submission and identified in **Tables 1** and **2**.

The proposed device and its predicate have similar intended use and technological characteristics. The differences raise no new concerns of safety and effectiveness when compared to the predicate device. New testing was performed to evaluate and demonstrate substantial equivalence to the predicate as summarized in **Table 3**.

Table 3. Performance Testing

Test	Acceptance Criteria	Result
In-Use Testing	Clinically used, cleaned semi-critical heat-sensitive medical devices exposed to varied clinical soils were effectively liquid chemically sterilized.	PASS
Electrical Safety Conformance	UL 61010-1:2012 Ed.3+R:29 Apr2016 Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements UL 61010-2-040:2016 Ed.2 Electrical Equipment For Measurement, Control, And Laboratory Use Part 2-040: Particular Requirements For Sterilizers And Washer-Disinfectors Used To Treat Medical Materials	PASS
Water Filter Performance through Use Life	The 0.2 micron MaxLife filter maintained its integrity and achieved effective bacterial retention performance after numerous Liquid Chemical Sterilization Cycles and Diagnostic Cycles representing 6 months of active use.	PASS
Water Filter Integrity Test	The Diagnostic Cycle correctly detects loss of filter integrity or absence of a filter.	PASS

Cycle Qualification	All cycle specifications were met for three (3) cycles each, Liquid Chemical Sterilization and Diagnostic.	PASS
Software Validation	The software that controls the system was validated and determined to operate effectively and as designed.	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 at least as well as the legally marketed predicate device (K170956), Class II (21 CFR 880.6885), product code MED.