DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 22, 2017

Steris Corporation
Tricia Cregger
Senior Manager, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K170956
Trade/Device Name: System 1E 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: August 25, 2017
Received: August 28, 2017

Dear Tricia Cregger:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S
2017.09.22 19:20:55 -04'00'

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)*
K170956

Device Name
SYSTEM 1E Liquid Chemical Sterilant Processing System

Indications for Use *(Describe)*
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 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 A is a gross depth filter that removes approximately 2.5 micron or larger particles/contaminants.
   - Pre-filter B 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 > 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.

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
For
SYSTEM 1E Liquid Chemical Sterilant Processing System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Tricia Cregger, Ph. D.
Senior Manager, Regulatory Affairs
Tel: 440-392-7189
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Summary Date: September 22, 2017

Premarket Notification Number: K170956

1. **Device Name**

Trade Name:	**SYSTEM 1E Liquid Chemical Sterilant Processing System**
Device Classification:	Class II
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**

SYSTEM 1E Liquid Chemical Sterilant Processing System cleared under K161683

3. **Description of Device**

The SYSTEM 1E Liquid Chemical Sterilant Processing System is a liquid chemical sterilization system, utilizing peracetic acid to process totally immersible, heat sensitive, flexible and rigid endoscopes and their accessories, and microsurgical instruments. The system consists of the SYSTEM 1E Processor and the S40 Sterilant Concentrate, interchangeable processing trays/containers and Quick Connects. The device was originally cleared under K090036. Five Special 510(k)s were cleared that subsequently made minor modifications to hardware, software, specifications, and labeling. This premarket notification introduces a new processing tray that will accommodate ultrasound endoscopes and other large flexible devices and their associated Quick Connects. Additionally, minor inconsistent statements in the cleared Indications for Use are corrected, and clarification is provided on post-processing handling and storage of critical and semi-critical medical devices.

The SYSTEM 1E Processor is an automated, self-contained device which creates and maintains the conditions necessary for liquid chemical sterilization in 6 minutes. Following processing, the liquid chemically sterilized articles are rinsed with extensively treated water produced by passing EPA potable tap water through pre-filters, an ultraviolet light treatment subsystem, and then through two 0.1 micron filter membranes. The processor, which is computer controlled and continually monitored, provides printed documentation of each cycle.

S40 Sterilant Concentrate is a single use chemical sterilant concentrate developed exclusively for use in the SYSTEM 1E Processor. The active ingredient in S40 Sterilant Concentrate, 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 instrument types, models and procedure specific sets. Each container is designed to maintain instruments in appropriate position while specific Quick Connects for the SYSTEM 1E Processor, if required, facilitate delivery of the liquid chemical sterilant use dilution and rinse water to internal channels.

4. Intended Use

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 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 A is a gross depth filter that removes approximately 2.5 micron or larger particles/contaminants.
   - Pre-filter B 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.

5. **Description of Technological Similarities and Differences**

The SYSTEM 1E Liquid Chemical Sterilant Processing System is the same as the predicate device except for the specific modification described in this submission. The differences between the proposed and predicate devices are limited to the addition of a new Ultrasound Processing Tray and the Quick Connects that enable the processing of large flexible ultrasound devices and labeling updates to correct errors and provide clarity to users and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

Device Comparison Table

Table 5-1. Processor Device Comparison Table

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
Indications for Use	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 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 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 46 to 55°C, and rinses the load with extensively treated* potable water. The processed load should be used immediately. 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	The minor differences between the Indications for Use for the proposed and predicate devices are for the correction of errors in the Indications for Use, for changes in designation of the pre-filters from 1 and 2 to A and B for consistency with all other labeling and to provide clarity for usage and storage of processed devices. There were no changes in performance.

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
	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 A is a gross depth filter that removes approximately 2.5 micron or larger particles/contaminants. • Pre-filter B 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.	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 SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	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. Sterilant Concentrate 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 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. Sterilant Concentrate 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 water to remove sterilant residuals.	Identical
Process Parameters	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temperature • Peracetic acid concentration • Bacterial retentive water filter integrity • UV irradiation	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temperature • Peracetic acid concentration • Bacterial retentive water filter integrity • UV irradiation	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	• 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	Identical

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
	probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification during Diagnostic cycle • Alarms if pressure transducer indicates 0.1 micron water filter failed integrity test during liquid chemical sterilant processing and Diagnostic cycles. • Alarms if UV monitor indicates UV intensity out of specification	probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification during Diagnostic cycle • Alarms if pressure transducer indicates 0.1 micron water filter failed integrity test during liquid chemical sterilant processing and Diagnostic cycles. • Alarms if UV monitor indicates UV intensity out of specification	
Design Features	• Microprocessor controlled unalterable and standardized liquid chemical sterilant processing and Diagnostic cycles • Intended for use with S40 Sterilant Concentrate • Processor provides dual 0.1 micron filtered, UV treated water for liquid chemical sterilant processing and rinsing • Automated dilution and delivery of sterilant • 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 sterilant processing and Diagnostic cycles • Intended for use with S40 Sterilant Concentrate • Processor provides dual 0.1 micron filtered, UV treated water for liquid chemical sterilant processing and rinsing • Automated dilution and delivery of sterilant • Make up air for processor during drain sequences is filtered through a 0.2 micron membrane air filter.	Identical
Processing Cycle			
Incoming water temperature	$\geq$ 43°C	$\geq$ 43°C	Identical
Temperature to start exposure phase	$\geq$ 46°C	$\geq$ 46°C	Identical

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
Temperature alarm point during the exposure phase	<45.5 or >60°C	<45.5 or >60°C	Identical
Temperature range during a typical Liquid Chemical Sterilant Processing Cycle	46 - 55°C	46 - 55°C	Identical
Exposure Time	6 minutes	6 minutes	Identical
Rinse water preparation	Hot potable tap water is: • pre-filtered • flowed through a UV Light treatment chamber to achieve ≥ a 6-log reduction of virus • Filtered through redundant 0.1 micron filter membranes	Hot potable tap water is: • pre-filtered • flowed through a UV Light treatment chamber to achieve ≥ a 6-log reduction of virus • Filtered through redundant 0.1 micron filter membranes	Identical
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
Water Filter Integrity Test	Conducted at the end of every liquid chemical sterilant processing cycle and during the Diagnostic cycle	Conducted at the end of every liquid chemical sterilant processing cycle and during the Diagnostic cycle	Identical
Approximate Cycle time	25 minutes	25 minutes	Identical

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
Diagnostic Cycle	Performs 15 tests on processor's systems confirming proper function (same tests as predicate device except for an added UV monitor test). Recommended to perform every 24 hours. After a failed Diagnostic cycle, a liquid chemical sterilant processing 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 (same tests as predicate device except for an added UV monitor test). Recommended to perform every 24 hours. After a failed Diagnostic cycle, a liquid chemical sterilant processing cycle cannot be performed until the problem is rectified and a successful Diagnostic cycle has been completed.	Identical
Interchangeable Components			
Processing Tray / Containers	Uses interchangeable processing trays/containers • Universal Flexible Processing Tray (C1160E) • General Processing Container/Tray (C1200) • Directed Flow Processing Container/Tray (C1220) • Flexible Endoscope Processing Container / Tray (C1140) • Ultrasound Processing Tray (C3000XL)	Uses interchangeable processing trays/containers • Universal Flexible Processing Tray (C1160E) • General Processing Container/Tray (C1200) • Directed Flow Processing Container/Tray (C1220) • Flexible Endoscope Processing Container / Tray (C1140)	The proposed device has available one more interchangeable tray than does the predicate device. This additional tray is designed for processing large ultrasound devices that do not fit into the other trays. Any new safety and efficacy concerns were addressed through verification testing.
Accessories			
Sterilant Concentrate	Uses S40 Sterilant Concentrate	Uses S40 Sterilant Concentrate	Identical
Quick Connects	Uses Quick Connects to adapt instrument lumens to the Tray/Container ports	Uses Quick Connects to adapt instrument lumens to the Tray/Container ports	The proposed device has additional Quick Connects to enable the processing of the larger ultrasound devices in the Ultrasound

Feature	Proposed SYSTEM 1E Processor	K161683 SYSTEM 1E Processor	Comparison
			Processing Tray. These Quick Connects function in a similar manner to currently marketed Quick Connects. Any new safety and efficacy concerns were addressed through verification testing.
Chemical Indicator	VERIFY Chemical Indicator for the SYSTEM 1E Processor (K102217)	VERIFY Chemical Indicator for the SYSTEM 1E Processor (K102217)	Identical
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant Concentrate (K100049)	VERIFY Spore Test Strip for S40 Sterilant Concentrate (K100049)	Identical
Operator Maintenance Requirements	Periodic replacement of printer tape, water filters and air filter	Periodic replacement of printer tape, water filters and air filter	Identical

Table 5-2. Sterilant Concentrate Device Comparison Table

Feature	Proposed S40 Sterilant Concentrate	K161683 S40 Sterilant Concentrate	Comparison
Indications for Use	S40 Sterilant Concentrate is for use only with the SYSTEM 1E Liquid Chemical Sterilant Processing System	S40 Sterilant Concentrate is for use only with the SYSTEM 1E Liquid Chemical Sterilant Processing System	Identical
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Germicide Exposure Time (min) for intended use	6	6	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

Feature	Proposed S40 Sterilant Concentrate	K161683 S40 Sterilant Concentrate	Comparison
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: -oxidizing sulfhydryl 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 sulfhydryl 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	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[5]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[6]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements[6]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[6]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Fungicidal Activity of	Solution is fungicidal. *Trichophyton*	Solution is fungicidal. *Trichophyton*	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) 83:269-276.
[6] McDonnell et al., J. AOAC International (2000) 83:269-276.

Feature	Proposed S40 Sterilant Concentrate	K161683 S40 Sterilant Concentrate	Comparison
Disinfectants AOAC Official Method 955.17	*mentagrophytes* Testing conducted *in vitro*	*mentagrophytes* Testing conducted *in vitro*	
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 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 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 $\log^{10}$ 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	No surviving microorganisms on representative medical devices tested	Identical
Biocompatibility			
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	Compatible with medical devices as established by testing finished flexible endoscopes through 300	Identical

Feature	Proposed S40 Sterilant Concentrate	K161683 S40 Sterilant Concentrate	Comparison
	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.	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.	
Chemical Monitoring	VERIFY Chemical Indicator for the SYSTEM 1E Processor(K102217)	VERIFY Chemical Indicator for the SYSTEM 1E Processor(K102217)	Identical
	Chemical reaction on indicator pad to produce color change.	Chemical reaction on indicator pad to produce color change.	Identical

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 the legally marketed predicate device (K161683), Class II (21 CFR 880.6885), product code MED.