April 8, 2026

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

Re: K251666
Trade/Device Name: SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700,
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid chemical sterilants/high level disinfectants
Regulatory Class: Class II
Product Code: MED
Dated: March 9, 2026
Received: March 9, 2026

Dear Jennifer Nalepka:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

KATHARINE SEGARS -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251666

Device Name
SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700

Indications for Use *(Describe)*
The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251666

Device Name
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900

Indications for Use *(Describe)*
The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, 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)

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510(k) Summary
For
SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 514-4509

Contact: Jennifer Nalepka
Manager, Regulatory Affairs
Phone: (440) 514-4509

Summary Date: April 7, 2026

Premarket Notification: K251666

1. **Device Name**

Trade Name:	SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700
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, K232914

Reference Device
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, K232914

3. **Description of Device**
The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700, 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.

This submission describes modifications to the processor's user interface and controller, introduced in the SYSTEM 1E Processor, Model P6700. The modifications will provide several user convenience features as compared to the originally cleared processor, model P6500. The advantages for users include an intuitive touchscreen display, a barcode scanner, and the ability to electronically save and download cycle data for facility records, or optionally to use a web-based data management system. The P6700 model utilizes an updated electronic controller and suitable software, while providing cycles for liquid chemical sterilization (LCS) and system diagnostics identical to those of the original device. The modified SYSTEM 1E Processor, which is computer controlled and continually monitored, provides electronic documentation of each cycle. An external printer is available for printed records, if preferred.

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 downloadable electronic documentation of each cycle.

S40 Sterilant Concentrate is a single use chemical sterilant concentrate developed 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. **Indications for Use**

The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700, 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.

5. **Technological Characteristic Comparison Table**

The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700, is the same as the predicate device with the exception of the proposed modification. A comparison between the proposed and predicate devices is included in **Table 1** and **Table 2**.

Table 1. Processor Device Comparison Table

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
Indications for Use	The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700 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.	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.	Identical

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
	• 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.	• 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.	
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:	Standardized cycle parameters cannot be altered by operator. The critical process parameters are:	Identical

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
	• Contact Time • Use Dilution Temperature • Peracetic acid concentration • Bacterial retentive water filter integrity • UV irradiation	• Contact Time • Use Dilution Temperature • Peracetic acid concentration • Bacterial retentive water filter integrity • UV irradiation	
Process Monitors	• Electronic cycle tape documents successful cycle completion or identifies fault if cycle aborts. An optional external printer is available to print cycle records. • Alarms if thermocouples indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if conductivity probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification 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	• 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 • 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	Identical, except for the cycle records are in electronic format.

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
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. • Includes a barcode reader for User to scan input data • Employs touchscreen display interface • Has a USB drive for download of electronic cycle records • Facilitates use of a web-based data management system • Separate, optional printer	• 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.	The proposed device uses an updated controller and its respective software for identical processing parameters. The proposed device incorporates a touchscreen display, barcode reader and USB drive for electronic cycle records, and facilitates use of a web-based data management system. Use of a printer is optional.
Processing Cycle			**Comparison**
Incoming water temperature	≥ 43°C	≥ 43°C	Identical
Temperature to start exposure phase	≥ 46°C	≥ 46°C	Identical
Temperature alarm point during the exposure phase	<45.5 or >60°C	<45.5 or >60°C	Identical
Temperature range during	46 - 55°C	46 - 55°C	Identical

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
a typical Liquid Chemical Sterilant Processing Cycle			
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. The default air purge length is 1 minute but can be extended up to 10 minutes by the user.	Aids in removing excess water from instrument lumens after rinsing. The air purge length is 1 minute.	Similar. The default air purge time is the same as the predicate with the option to extend it.
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	23 minutes	23 minutes	Identical
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

Feature	Proposed SYSTEM 1E Processor, Model P6700	Predicate (K232914) SYSTEM 1E Processor, Model P6500	Comparison
Accessories			
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) • Ultrasound Processing Tray (C3000XL)	Identical
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	Identical
Chemical Indicator	VERIFY Chemical Indicator for the S40 Sterilant Concentrate	VERIFY Chemical Indicator for the S40 Sterilant Concentrate	Identical
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant Concentrate	VERIFY Spore Test Strip for S40 Sterilant Concentrate	Identical
Operator Maintenance Requirements	Periodic replacement of water filters and air filter. Periodic replacement of printer tape if using optional external printer.	Periodic replacement of printer tape, water filters and air filter	Identical, except for the replacement of printer tape, which is only applicable if using the optional external printer.

Table 2. S40 Sterilant Concentrate Device Comparison Table

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
Indications for Use for S40 Sterilant Concentrate	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	Identical
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Germicide Exposure Time (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
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

[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.

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
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[5]. *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 Disinfectants AOAC Official Method 955.17	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Identical
Use Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Identical
EPA Viricidal Testing (DIS/TSS-7, Nov. 1981)	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Identical
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae* Testing conducted *in vitro*	Solution is tuberculocidal *Mycobacterium terrae* Testing conducted *in vitro*	Identical
Simulated-Use Test	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Identical

[5] McDonnell et al., J. AOAC International (2000) 83:269-276.

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
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 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Compatible with medical devices as established by testing finished flexible endoscopes through 300 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Identical

Table 3. Proposed and Reference Device Comparison

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
Intended Use **Indications for Use**	The SYSTEM 1E Liquid Chemical Sterilant Processing System, Model P6700, 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),	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 in healthcare facilities. The SYSTEM 1 endo Processor dilutes the S40 Sterilant Concentrate to its use dilution (>1820 mg/L peracetic acid), liquid chemically sterilizes the	Reference device's intended use is limited to semi-critical medial devices and their accessories.

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
	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-	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.	

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
	micron (absolute rated) membranes to remove bacteria, fungi and protozoa > 0.1 micron.		
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, 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.	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	Identical, except there is no UV system intensity to be monitored in the reference device.

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
Process Monitors	• Electronic cycle tape documents successful cycle completion or identifies fault if cycle aborts. An optional printer is available to print cycle records. • Alarms if thermocouples indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if conductivity probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification 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	• Electronic cycle tape documents successful cycle completion or identifies fault if cycle aborts. • Alarms if thermocouples indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if conductivity probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification during Diagnostic cycle • Alarms if pressure transducer indicates internal water filter failed integrity test	Identical, except there is no UV system intensity to be monitored in the reference device.
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 0.1-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 0.2-micron filtered water for liquid chemical sterilant processing and rinsing • Automated dilution and delivery of sterilant • Make-up air for the processor during drain sequences is filtered through a 0.2-micron membrane air filter. • Includes a barcode reader for User to scan input data	Identical except: • The proposed device uses a web-based data management system. • The reference device does not provide extensively treated water.

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
	• Includes a barcode reader for User to scan input data • Employs touchscreen display interface • Has a USB drive for download of electronic cycle records • Facilitates use of a web-based data management system • Separate, optional printer	• Employs touchscreen display interface • Has a USB drive for download of electronic cycle records • Separate, optional printer for cycle records	
Cycle Parameters			
Incoming water temperature	> 43°C	≥ 43°C	Identical
Temperature to start exposure phase	≥ 46°C	≥ 46°C	Identical
Temperature alarm point during 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 • Filtered through 0.2-micron bacterial retentive filter	The reference 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. The default air purge length is 1 minute but can be extended up to 10 minutes by the user.	Aids in removing excess water from instrument lumens after rinsing.	Identical intended use of the air purge

Feature	Proposed SYSTEM 1E Processor, Model P6700	Reference (K232914) SYSTEM 1 endo Processor, Model P6900	Comparison
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	23 minutes	18-20 minutes	Similar, the proposed device utilizes a UV-light
Diagnostic Cycle	Performs 15 tests on processor's systems confirming proper function. 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 14 tests on processor's systems confirming proper function. 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 except the reference device does not perform the UV intensity monitor test.
Accessories			
Processing Trays/ 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) • Ultrasound Processing Tray (C3000XL)	Identical
Sterilant	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	Identical
Chemical Indicator	VERIFY Chemical Indicator for SYSTEM 1E and SYSTEM 1 endo Liquid Chemical Sterilant Processing Systems	VERIFY Chemical Indicator for SYSTEM 1E and SYSTEM 1 endo Liquid Chemical Sterilant Processing Systems	Identical
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant Concentrate	VERIFY Spore Test Strip for S40 Sterilant Concentrate	Identical
Operator Maintenance Requirements	Periodic replacement of water filters and air filter. Periodic replacement of printer tape if using optional external printer.	Periodic replacement of printer tape, water filters and air filter.	Identical

The proposed device and its predicate have identical intended use and technological characteristics. New testing was performed to evaluate the modified device, and the results are summarized in **Table 4**.

6. Summary of Non-Clinical Testing

Shown in **Table 4** is the new testing that was performed to evaluate the modified device.

Table 4. Summary of verification activities.

Test	Acceptance Criteria	Result
Software Validation	Meets requirements per: • ANSI/AAMI/IEC 62304:2006/A1:2016, Medical device software – Software life cycle processes [Including Amendment 1(2016)]	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 60601-1-2:2015, +A1:2021 Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.	Pass
Cybersecurity	No vulnerabilities with CVSS score of medium or above exist on the system	Pass
Biocompatibility	Meets requirements per: ISO 10993-1:2018, Biological evaluation of medical devices – Evaluation and testing within a risk management process	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 or better than the legally marketed predicate device (K232914), Class II (21 CFR 880.6885), product code MED.

510(k) Summary
For
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
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Contact: Jennifer Nalepka
Manager, Regulatory Affairs
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Summary Date: April 7, 2026

Premarket Notification: K251666

1. Device Name

Trade Name:	**SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900**
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

SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, K232914

3. Description of Device

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 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.

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. After LCS 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 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. **Tables 1** and **2** compare the proposed and predicate devices.

4. Indications for Use

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, 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. Technological Characteristic Comparison Table

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System (LCSPS) is the same as the predicate device with the exception of the proposed modification. A comparison between the proposed and predicate devices can be found in **Table 1** and **Table 2** below. Since there are no technological differences between the proposed and predicate devices, there are no new concerns of safety and effectiveness.

Table 1. Processor Comparison Table

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K232914)	Comparison
Intended Use **Indications for Use**	The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, 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.	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.	Identical

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K232914)	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 0.2 micron filtered water to remove sterilant residuals.	Identical
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

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K232914)	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	
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 • Includes a barcode scanner; employs touchscreen display interface; has USB drive for electronic cycle download; facilitates use of a web-based data management system. • Separate, optional printer	• 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 • Includes a barcode scanner; employs touchscreen display interface; has USB drive for electronic cycle download; facilitates use of a web-based data management system. • Separate, optional printer	Identical
Cycle Parameters			**Comparison**
Incoming water temp.	≥ 43°C	≥ 43°C	Identical
Temperature to start sterilant exposure	≥ 46°C	≥ 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

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K232914)	Comparison
Exposure Time – S40 use dilution	6 minutes	6 minutes	Identical
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 • is filtered through 0.2 micron bacterial retentive membrane filter	Identical
Number of rinses	2	2	Identical
Air Purge	Aids in removing excess water from instrument lumens after rinsing. The default air purge length is 1 minute but can be extended up to 10 minutes by the user.	Aids in removing excess water from instrument lumens after rinsing. The default air purge length is 1 minute but can be extended up to 10 minutes by the user.	Identical
Internal Water Filter Integrity Test	Conducted during the Diagnostic cycle	Conducted during the Diagnostic cycle	Identical
Approximate Cycle Time	18 - 20 minutes	18 - 20 minutes	Identical
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 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.	Identical
Accessories			**Comparison**
Sterilant	Uses S40 Sterilant Concentrate	Uses S40 Sterilant Concentrate	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 • Ultrasound Processing Tray	Uses interchangeable processing trays/containers • Universal Flex Processing Tray • General Processing Container & Tray • Directed Flow Processing Container & Tray • Flexible Endoscope Processing Container & Tray • Ultrasound Processing Tray	Identical
Quick Connects	Uses Quick Connects to attach instrument lumens to the	Uses Quick Connects to attach instrument lumens to the	Identical

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K232914)	Comparison
	Tray/Container ports	Tray/Container ports	
Chemical Indicator	VERIFY Chemical Indicator for S40 Sterilant is available for use in SYSTEM 1 endo LCSPS	VERIFY Chemical Indicator for S40 Sterilant is available for use in SYSTEM 1 endo LCSPS	Identical
Spore Test Strip	VERIFY Spore Test Strip for S40 Sterilant for use in SYSTEM 1 endo LCSPS	VERIFY Spore Test Strip for S40 Sterilant for use in SYSTEM 1 endo LCSPS	Identical
Operator Maintenance	Periodic replacement of water filters and air filter. Periodic replacement of printer tape, if using the external printer option.	Periodic replacement of water filters and air filter. Periodic replacement of printer tape, if using the external printer option.	Identical

Table 2. S40 Sterilant Concentrate Comparison Table

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
Indications for Use for S40 Sterilant Concentrate	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	Identical
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Germicide Exposure Time (min) for intended use	6	6	Identical
Use Temperature	45.5-60°C – allowable 46-55°C - typical Potency and simulated use evaluations conducted at ≤43°C	45.5-60°C – allowable 46-55°C - typical Potency and simulated use evaluations conducted at ≤43°C	Identical
Reuse	Single use	Single use	Identical
Human Factors	Dispensed ready to use. Container is opened and diluted by the processor, thus limiting user exposure to the active ingredient	Dispensed ready to use Container is opened and diluted by the processor, thus limiting user exposure to the active ingredient	Identical
Active Ingredient	35% peroxyacetic (peracetic) acid automatically diluted for use in the SYSTEM 1E Processor.	35% peroxyacetic (peracetic) acid automatically diluted for use in the SYSTEM 1E Processor.	Identical
Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydryl and sulfur	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydryl and sulfur	Identical

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
	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].	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]	
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[5]. *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 Disinfectants AOAC Official Method 955.17	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*	Identical
Use Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Identical
EPA Viricidal Testing (DIS/TSS-7, Nov. 1981)	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Solution is viricidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Identical
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal Mycobacterium terrae Testing conducted *in vitro*	Solution is tuberculocidal Mycobacterium terrae Testing conducted *in vitro*	Identical
Simulated-Use Test	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus*	Meets efficacy requirement. $\geq$ 6 log reduction *Geobacillus*	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.

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K232914)	Comparison
	stearothermophilus spores in a manual application	*stearothermophilus* spores in a manual application	
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 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Compatible with medical devices as established by testing finished flexible endoscopes through 300 cycles and rigid devices through 150 cycles. No functional changes have occurred to flexible devices. Some materials show cosmetic changes such as fading of black anodized aluminum without harm to the base material.	Identical

6. Summary of Non-Clinical testing

Shown in **Table 3** is the new testing that was performed to evaluate the modified device.

Table 3. Summary of verification activities

Test	Acceptance Criteria	Result
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 60601-1-2:2015, +A1:2021 Medical Electrical Equipment, Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.	Pass
Cybersecurity	No vulnerabilities with CVSS score of medium or above exist on the system	Pass
Biocompatibility	Meets requirements per: ISO 10993-1:2018, Biological evaluation of medical devices – Evaluation and testing within a risk management process	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 or better than the legally marketed predicate device (K232914), Class II (21 CFR 880.6885), product code MED.