September 7, 2021

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

Re: K211607
Trade/Device Name: SYSTEM 1E Liquid Chemical Sterilant Processing System, SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6800, SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900, S40 Sterilant Concentrate
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: Class II
Product Code: MED
Dated: September 1, 2021
Received: September 2, 2021

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211607

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 > or equal to 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211607

Device Name
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6800

Indications for Use *(Describe)*
The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211607

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 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

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Jennifer Nalepka
Lead Regulatory Affairs Specialist
Tel: 440-392-7458
Fax: 440-357-9198

Summary Date: September 1, 2021

Premarket Notification Number: K211607

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, K210737

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 current submission is provided to describe modifications for:

- Obsolescence and replacement of interface board and connector
- Obsolescence and replacement of silicone tubing
- S40 Sterilant Concentrate design modification

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 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 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. Technological Characteristic Comparison Table

The SYSTEM 1E Liquid Chemical Sterilant Processing System is the same as the predicate device; the specific modifications described in this submission are for a firmware update and obsolescence to components.

Table 1. Processor Device Comparison Table

Feature	Proposed SYSTEM 1E Processor	Predicate (K210737) 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 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:	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:	Identical

Feature	Proposed SYSTEM 1E Processor	Predicate (K210737) SYSTEM 1E Processor	Comparison
	• 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.	• 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: • 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	• Cycle Printout documents successful cycle completion	Identical

Feature	Proposed SYSTEM 1E Processor	Predicate (K210737) SYSTEM 1E Processor	Comparison
	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	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	
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			**Comparison**
Incoming water temperature	$\geq$ 43°C	$\geq$ 43°C	Identical

Feature	Proposed SYSTEM 1E Processor	Predicate (K210737) SYSTEM 1E Processor	Comparison
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 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
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			

Feature	Proposed SYSTEM 1E Processor	Predicate (K210737) SYSTEM 1E Processor	Comparison
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
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	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 printer tape, water filters and air filter	Periodic replacement of printer tape, water filters and air filter	Identical

Table 2. S40 Sterilant Concentrate Device Comparison Table

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K210737)	Comparison
Indications for Use	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

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K210737)	Comparison
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[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

[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 (K210737)	Comparison
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. ≥ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Meets efficacy requirement. ≥ 6 log 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 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	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	Identical

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K210737)	Comparison
	anodized aluminum without harm to the base material.	anodized aluminum without harm to the base material.	

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 3**.

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.

Change	Test	Acceptance Criteria	Result
Obsolescence and replacement of interface board and connector	Functional testing	The modification does not affect the operation of the device.	Pass
	Reliability testing	The modification does not affect the operation of the device.	Pass
	EMC/EMI and electrical safety	The device must meet UL 61010-1:2010 Third Edition and UL 61010-2-040:2015-7-07	Pass
Obsolescence and replacement of silicone tubing	Functional testing	The modification does not affect the operation of the device	Pass
	Form and fit	The replacement must fit within the device	Pass
	Physical properties	The replacement must be equivalent to the current tubing	Pass
S40 Sterilant Concentrate design modification	Stability of sterilant	The design modification does not affect the stability of the sterilant.	Pass
	Delivery of sterilant	The design modification does not affect delivery of the sterilant.	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 (K210737), Class II (21 CFR 880.6885), product code MED.

510(k) Summary
For
SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6800

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Summary Date: September 1, 2021

Premarket Notification Number: K211607

1. Device Name

Trade Name:	SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6800
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 1endo Liquid Chemical Sterilant Processing System, Model P6800, K210737

3. Description of Device

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is a liquid chemical sterilization system, utilizing peracetic acid to process totally immersible semi-critical 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 current submission is provided to describe modifications for:

- Obsolescence and replacement of silicone tubing
- S40 Sterilant Concentrate design modification

The SYSTEM 1 endo Processor is an automated, self-contained device that uses S40 Sterilant Concentrate to create and maintain the conditions necessary for liquid chemical sterilization in 6 minutes. Following processing, the liquid chemically sterilized articles are rinsed with 0.2 micron filtered potable water and are ready for use or may be prepared for storage. The processor, which is computer controlled and continually monitored, provides printed documentation of each cycle.

The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate. Upon loading the single-use cup, the active ingredient in S40 – peracetic acid – is combined with inert ingredients (builders) to form a use dilution which inhibits corrosion of metals, polymers and other materials.

The interchangeable processing trays/containers are made to accommodate a variety of semi-critical instrument types and models. Each container is designed to maintain instruments in position while specific SYSTEM 1 endo Quick Connects, if

required, facilitate delivery of the sterilant use-solution and rinse water to internal channels. **Table 1** compares the proposed and predicate devices.

4. Intended Use

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical medical devices and their accessories 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 load during a controlled 6-minute exposure at 45.5 to 55°C, and rinses the load with 0.2 micron filtered potable water.

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

5. Description of Technological Similarities and Differences

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is identical to the predicate device. A comparison between the proposed and predicate devices is included in **Table 1** and **Table 2**. 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 Processor, Model P6800	Predicate Device (K210737) SYSTEM 1 endo Processor, Model P6800	Comparison
Intended Use **Indications for Use**	The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical 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 Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical 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.	Identical

Feature	Proposed Device SYSTEM 1 endo Processor, Model P6800	Predicate Device (K210737) SYSTEM 1 endo Processor, Model P6800	Comparison
	The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	The SYSTEM 1 endo Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	
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 the operator. The critical process parameters are: • Use dilution contact time • Use dilution temperature • Peracetic acid concentration • Bacterial retentive water filter integrity	Standardized cycle parameters cannot be altered by the operator. The critical process parameters are: • Use dilution contact time • Use dilution temperature • Peracetic acid concentration • Bacterial retentive water filter integrity	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	• 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	Identical

Feature	Proposed Device SYSTEM 1 endo Processor, Model P6800	Predicate Device (K210737) SYSTEM 1 endo Processor, Model P6800	Comparison
	• Alarms if conductivity probe indicated conductivity specification not met • 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 conductivity probe indicated conductivity specification not met • 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 sterilant process and rinsing • Make-up air for processor during drain sequences is filtered through a 0.2 micron membrane filter	• Microprocessor controlled unalterable and standardized liquid chemical sterilization and Diagnostic cycles • Intended for use only with S40 Sterilant Concentrate • Automated dilution and delivery of S40 Sterilant • Processor provides 0.2 micron filtered water for liquid chemical sterilant process and rinsing • Make-up air for processor during drain sequences is filtered through a 0.2 micron membrane filter	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°C or > 60°C	< 45.5°C or > 60°C	Identical
Temperature range of typical LCS cycle	46-55°C	46-55°C	Identical

Feature	Proposed Device SYSTEM 1 endo Processor, Model P6800	Predicate Device (K210737) SYSTEM 1 endo Processor, Model P6800	Comparison
Rinse water preparation	Hot potable water • is pre-filtered • is filtered through 0.2 micron bacterial retentive filter	Hot potable water • is pre-filtered • is filtered through 0.2 micron bacterial retentive filter	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
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 – See **Table 2**	Uses S40 Sterilant Concentrate – See **Table 2**	Identical
Processing Trays and Containers	Uses interchangeable processing trays/containers • Universal Flexible Processing Tray • General Processing Container and Tray • Directed Flow Processing Container and Tray • Flexible Endoscope Processing Container and Tray • Ultrasound Processing Tray	Uses interchangeable processing trays/containers • Universal Flexible Processing Tray • General Processing Container and Tray • Directed Flow Processing Container and Tray • Flexible Endoscope Processing Container and Tray • Ultrasound Processing Tray	Identical

Feature	Proposed Device SYSTEM 1 endo Processor, Model P6800	Predicate Device (K210737) SYSTEM 1 endo Processor, Model P6800	Comparison
Quick Connects	Uses Quick Connects to attach instrument lumens to the Tray/Container ports	Uses Quick Connects to attach instrument lumens to the Tray/Container ports	Identical
Chemical Indicator	VERIFY Chemical Indicator 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 printer tape, water filters and air filter	Periodic replacement of printer tape, water filters and air filter	Identical

Table 2. S40 Sterilant Concentrate Comparison Table

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K210737)	Comparison
Indications for Use	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

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K210737)	Comparison
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[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

[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 (K210737)	Comparison
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. ≥ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Meets efficacy requirement. ≥ 6 log 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 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. Description of Safety and Substantial Equivalence

The SYSTEM endo Liquid Chemical Sterilant Processing System is the same as the predicate device as identified in **Tables 1** and **2**.

The proposed device and its predicate have identical intended use and technological characteristics. Testing was performed to evaluate the modifications and demonstrate substantial equivalence to the predicate as summarized in **Table 3**.

Table 3. Performance Testing

Change	Test	Acceptance Criteria	Result
Obsolescence and replacement of silicone tubing	Functional testing	The modification does not affect the operation of the device	Pass
	Form and fit	The replacement must fit within the device	Pass
	Physical properties	The replacement must be equivalent to the current tubing	Pass
S40 Sterilant Concentrate design modification	Stability of sterilant	The design modification does not affect the stability of the sterilant.	Pass
	Delivery of sterilant	The design modification does not affect delivery of the sterilant.	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 (K210737), Class II (21 CFR 880.6885), product code MED.

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

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Summary Date: September 1, 2021

Premarket Notification Number: K211607

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, K210737.

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 current submission is provided to describe modifications for:

- Obsolescence and replacement of silicone tubing
- S40 Sterilant Concentrate design modification

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 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; the submission is for modifications to the SYSTEM 1 endo LCSPS software. A comparison between the proposed and predicate devices can be found in **Table 1** and **Table 2** below.

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 (K210737)	Comparison
Intended Use **Indications for Use**	The SYSTEM 1 endo Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable semi-critical heat-sensitive medical devices and their accessories in healthcare facilities. The SYSTEM 1 endo Processor automatically dilutes the S40 Sterilant Concentrate to its use dilution (> 1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 45.5 to 60°C, and rinses the load with 0.2 micron filtered water. The SYSTEM 1 endo Processor uses only S40 Sterilant	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	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 (K210737)	Comparison
	Concentrate to liquid chemically sterilize medical devices.	Concentrate to liquid chemically sterilize medical devices.	
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	• 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	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 (K210737)	Comparison
	• Alarms if conductivity probe indicated conductivity specification not met • 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 conductivity probe indicated conductivity specification not met • 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	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 (K210737)	Comparison
range of typical LCS cycle			
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	Aids in removing excess water from instrument lumens after rinsing	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 (K210737)	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 (K210737)	Comparison
Indications for Use	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 (K210737)	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	Solution is tuberculocidal	Solution is tuberculocidal	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 (K210737)	Comparison
Activity Ascenzi Quantitative Suspension Test	Mycobacterium terrae Testing conducted *in vitro*	Mycobacterium terrae Testing conducted *in vitro*	
Simulated-Use Test	Meets efficacy requirement. ≥ 6 log reduction *Geobacillus stearothermophilus* spores in a manual application	Meets efficacy requirement. ≥ 6 log 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 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. Description of Safety and Substantial Equivalence

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 is the same as the predicate device described in this submission and identified in **Tables 1** and **2**.

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 3**.

Table 3. Summary of verification activities

Change	Test	Acceptance Criteria	Result
Obsolescence and replacement of silicone tubing	Functional testing	The modification does not affect the operation of the device	Pass
	Form and fit	The replacement must fit within the device	Pass
	Physical properties	The replacement must be equivalent to the current tubing	Pass
S40 Sterilant Concentrate design modification	Stability of sterilant	The design modification does not affect the stability of the sterilant.	Pass
	Delivery of sterilant	The design modification does not affect delivery of the sterilant.	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 (K210737), Class II (21 CFR 880.6885), product code MED.