March 28, 2023

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

Re: K230582
Trade/Device Name: SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900
Regulation Number: 21 CFR 880.6885
Regulation Name: Sterilant, Medical Devices, Liquid Chemical Sterilants/Disinfectants
Regulatory Class: Class II
Product Code: MED
Dated: March 1, 2023
Received: March 2, 2023

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,

Clarence W. Murray III -S

Clarence W. Murray III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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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)*
K230582

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

K230582

STERIS Corporation
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Contact: Jennifer Nalepka
Manager, Regulatory Affairs
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Summary Date: March 1, 2023

1. **Device Name**

Trade Name:	SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900
Device Class:	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 1 endo Liquid Chemical Sterilant Processing System, Model P6900, K222615

3. **Description of Device**

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (S1 endo) 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 S1 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 S1 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 S1 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. Technical Characteristic Comparison Table

The S1 endo 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.

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 (K222615)	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 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
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.	• 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.	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 (K222615)	Comparison
	• 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.	• 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.	
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 • 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	• 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 in Diagnostic cycle • Alarms if pressure transducer indicates internal water filter failed integrity test	Identical
Design Features	• Microprocessor controlled unalterable and standardized	• Microprocessor controlled unalterable and standardized	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 (K222615)	Comparison
	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	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	
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
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

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 (K222615)	Comparison
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 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

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 (K222615)	Comparison
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 (K222615)	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 bonds in proteins and enzymes, particularly in the cell walls [1] -hydroxyl radicals produced from PAA are bactericidal [2]	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]	Identical

[1] Block, S. ed., Disinfection, Sterilization, and Preservation. 5th edition, 2001.
[2] Clapp et al., Free Rad. Res., (1994) 21:147-167.

Feature	Proposed Device S40 Sterilant Concentrate	Predicate Device S40 Sterilant Concentrate (K222615)	Comparison
	-PAA damages the viral capsid and viral nucleic acid[3,4].	-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

[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 (K222615)	Comparison
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

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are to use control boards that have been slightly modified by using alternative, drop-in replacement components in the manufacture of the devices.

6. Summary of Non-Clinical Testing

Non-clinical performance testing was performed according to the test methodology listed below and is the same methods used to verify the original design. The testing demonstrated that the subject device met the acceptance criteria described in the standard/methodology.

Table 3. Summary of Non-Clinical Testing

Test	Criterion	Conclusion
Use of new control boards	New control boards must fit and run all cycles without alarms	Pass
Software confirmation test	Ensure proper version, proper operation of cycles and alarms	Pass

7. Conclusion

The conclusions drawn from the non-clinical performance data, the SYSTEM 1 endo Liquid Chemical Sterilant Processing System is as safe, as effective, and performs as well or better than the legally marketed predicate device K222615, Class II (21 CFR 880.6885), product code MED.