September 5, 2019

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

Re: K191343
Trade/Device Name: SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: Class II
Product Code: MED
Dated: September 4, 2019
Received: September 4, 2019

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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.

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

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

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

Submission Date: August 29, 2019

Premarket Notification Number: K191343

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, K182827.

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 certain software modifications made after the clearance of K182827.

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 (K182827)	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	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	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 (K182827)	Comparison
	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.	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.	
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

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 (K182827)	Comparison
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 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

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 (K182827)	Comparison
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
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	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	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 (K182827)	Comparison
	successful Diagnostic cycle has been completed.	successful Diagnostic cycle has been completed.	
Accessories			**Comparison**
Sterilant	Uses S40 Sterilant Concentrate – see **Table 2**	Uses S40 Sterilant Concentrate – see **Table 2**	Identical
Processing Trays and Containers	Uses interchangeable processing trays/containers • Universal Flex Processing Tray • General Processing Container & Tray • Directed Flow Processing Container & Tray • Flexible Endoscope Processing Container & Tray • 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
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 SYSTEM 1 endo Liquid Chemical Sterilant Processing System , Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K182827)	Comparison
Intended Use	For use in S1E or S1 endo LCSPS	For use in S1E or S1 endo LCSPS	Identical
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	Identical
Exposure Time	6 minutes	6 minutes	Identical
Use Temperature	45.5 - 60ºC – allowable range Potency and simulated use evaluations conducted at ≤ 43°C	45.5 - 60ºC – allowable range Potency and simulated use evaluations conducted at ≤ 43°C	Identical
Reuse	Single use	Single use	Identical
Human Factors	Ready to use. Container is opened and diluted by the processor, limiting user exposure to the sterilant concentrate	Ready to use. Container is opened and diluted by the processor, limiting user exposure to the sterilant concentrate	Identical
Active Ingredient	35% peroxyacetic (peracetic) acid automatically diluted for use in the Processor	35% peroxyacetic (peracetic) acid automatically diluted for use in the Processor	Identical
Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls [1] -hydroxyl radicals produced from PAA are bactericidal [2] -PAA damages the viral capsid and viral nucleic acid[3,4]	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydral and sulfur bonds in proteins and enzymes, particularly in the cell walls[1] -hydroxyl radicals produced from PAA are bactericidal[2] -PAA damages the viral capsid and viral nucleic acid[3.4]	Identical
Rinses	2 equivalent automated rinses with pre-filtered, dual 0.2 micron membrane filtered, potable hot water	2 equivalent automated rinses with pre-filtered, dual 0.2 micron membrane filtered, potable hot water	Identical

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

Feature	Proposed Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System , Model P6900	Predicate Device SYSTEM 1 endo Liquid Chemical Sterilant Processing System, Model P6900 (K182827)	Comparison
Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Meets efficacy requirements[5] *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*	Identical
Fungicidal Activity of Disinfectants AOAC Official Method 955.17	Solution is fungicidal *Trichophyton mentagrophytes* Testing conducted *in vitro*	Solution is fungicidal *Trichophyton mentagrophytes* Testing conducted *in vitro*	Identical
Use Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Solution is bactericidal *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*	Identical
EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	Solution is virucidal Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Solution is virucidal Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1 Testing conducted *in vitro*	Identical

[5] McDonnell et al., J. AOAC International (2000) 83:269-275

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 (K182827)	Comparison
Tuberculocidal Activity of Disinfectants AOAC Official Method 965.12	Not performed; a quantitative suspension Tuberculocidal test was conducted	Not performed; a quantitative suspension Tuberculocidal test was conducted	Identical
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae* testing conducted *in vitro*	Solution is tuberculocidal *Mycobacterium terrae* testing conducted *in vitro*	Identical
Simulated Use	Meets efficacy requirement. $\geq$ 6 $\log^{10}$ reduction *Geobacillus stearothermophilus* spores in a manual application.	Meets efficacy requirement. $\geq$ 6 $\log^{10}$ reduction *Geobacillus stearothermophilus* spores in a manual application.	Identical
Clinical In Use	No surviving microorganisms on representative medical devices tested in S1 endo LCSPS	No surviving microorganisms on representative medical devices tested in S1 endo LCSPS	Identical
Cytotoxicity Device Extracts	Two Processor controlled rinses with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to non-cytotoxic levels.	Two Processor controlled rinses with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to non-cytotoxic levels.	Identical
Residue Reduction	Two Processor controlled rinses with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to safe levels.	Two Processor controlled rinses with pre-filtered, dual 0.2 micron filtered potable water effectively reduce sterilant residues to safe levels.	Identical
Material Compatibility	Compatible with medical devices as established by testing finished medical devices through 300 cycles. No functional changes occurred to devices. Some materials show cosmetic changes such as fading of external markings (yet all remained legible) and bleaching of black anodized aluminum without harm to the base material.	Compatible with medical devices as established by testing finished medical devices through 300 cycles. No functional changes occurred to devices. Some materials show cosmetic changes such as fading of external markings (yet all remained legible) and bleaching of black anodized aluminum without harm to the base material.	Identical

6. Description of Nonclinical Testing

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

Test	Acceptance Criteria	Result
Software Validation	The software that controls the system was validated and determined to operate effectively and as designed.	**Pass**

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K182827).