Appendix 2

APR - 5 2010

Revised 510(k) Summary

STERIS®

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

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Summary Date: April 1, 2010

1. Device Name

Trade Name:	**SYSTEM 1E Liquid Chemical Sterilant Processing System**
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

STERIS SYSTEM 1 PROCESSOR and STERIS 20 STERILANT, K875280, cleared September 13, 1988.

Sterilox Liquid Chemical High Level Disinfection System, K013280, cleared September 18, 2002

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 SYSTEM 1E Processor is an automated, self-contained device which creates and maintains the conditions necessary for liquid chemical sterilization in 6 minutes. Following the 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 system, and then through two 0.1 micron filter membranes. The processor, which is computer controlled and continually monitored, provides printed documentation of each cycle.

S40 Sterilant Concentrate is a single use chemical sterilant concentrate developed exclusively for use in the SYSTEM 1E Processor. The active ingredient in S40, peracetic acid, is combined with inert ingredients 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 ensure thorough circulation of the sterilant solution and rinses.

4. Intended Use

The SYSTEM 1E Liquid Chemical Sterilant Processing System is intended for liquid chemical sterilization of cleaned, immersible, and reusable critical and semi-critical heat-sensitive medical devices in healthcare facilities.

The SYSTEM 1E Processor dilutes the S40 Sterilant Concentrate to its use dilution (>1820 mg/L peracetic acid), liquid chemically sterilizes the load during a controlled 6-minute exposure at 46 to 55°C, and rinses the load with extensively treated* potable water. The processed load should be used immediately.

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

* The extensive treatment of EPA potable water consists of:

1. Pre-filtration through two pre-filters:
   - Pre-filter 1 is a gross depth filter that removes approximately 5 micron or larger particles/contaminants.
   - Pre-filter 2 is a surface filter that removes particles/contaminants > 0.1 micron.
2. UV Irradiation:
   - During transit through the UV Water Treatment Chamber, a UV dose sufficient to achieve a $\geq$ 6-log reduction of MS2 virus is delivered to the water.
3. 0.1 micron filtration:
   - The water prepared by pre-filtration and UV irradiation is filtered through redundant, 0.1-micron (absolute rated) membranes to remove bacteria, fungi and protozoa > 0.1 micron.

5. Description of Safety and Substantial Equivalence

The SYSTEM 1E Processor and S40 Sterilant Concentrate are substantially equivalent in function and intended use to the STERIS SYSTEM 1 and STERIS 20 Sterilant and Sterilox Liquid Chemical High Level Disinfection System.

Device Comparison Table

Table 5-1. Processor Device Comparison Table

Feature	SYSTEM 1E Processor	SYSTEM 1 Processor(K875280)
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 automatically dilutes the S40 Sterilant Concentration to its use dilution (≥1820 mg/L peracetic acid) and liquid chemically sterilizes the load during a controlled 6-minute exposure at 46 to 55°C and rinses the load with extensively treated potable water. The processed load should be used immediately. The SYSTEM 1E Processor uses only S40 Sterilant Concentrate to liquid chemically sterilize medical devices.	The SYSTEM 1 is a liquid chemical sterilization system used for the rapid liquid chemical sterilization of clean reusable immersible medical devices such as flexible and rigid endoscopes, and other medical and dental devices in hospitals, medical, surgical and dental clinics/offices.
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 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 potable water to remove sterilant residuals.	
Process Parameters	Standardized cycle parameters cannot be altered by operator. The critical process parameters are: • Contact Time • Use Dilution Temperature • Peracetic acid concentration • Dual membrane, 0.1 micron 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 • 0.2 micron water filter integrity

Feature	SYSTEM 1E Processor	SYSTEM 1 Processor(K875280)
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 during Diagnostic cycle • Alarms if pressure transducer indicates dual membrane 0.1 micron water filter failed integrity test during liquid chemical sterilization processing and Diagnostic cycles • Alarms if UV monitor indicates UV intensity out of specification	• Cycle Printout documents successful cycle completion or identifies fault if cycle aborts • Alarms if thermocouples indicate temperature out of specification • Alarms if pressure switch indicates that high pressure pump is not operating • Alarms if conductivity probe indicated conductivity specification not met • Alarms if pressure transducer indicates circulation pressure is out of specification during Diagnostic cycle • Alarms if pressure transducer indicates sterile water filter failed integrity test during Diagnostic cycle
Design Features	• Microprocessor controlled unalterable and standardized liquid chemical sterilization and diagnostic cycles • Intended for use with S40 Sterilant Concentrate • Processor provides dual 0.1 micron membrane filtered, UV treated water for liquid chemical sterilization 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 sterilization and diagnostic cycles • Intended for use with STERIS 20 Sterilant Concentrate only. • Processor provides 0.2 micron filtered water for liquid chemical sterilization 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.
Liquid Chemical Sterilization Cycle		
Incoming water temperature	≥ 43°C	≥ 42°C
Temperature to start sterilant exposure	≥ 46°C	≥ 50°C
Temperature alarm point during the sterilant exposure	<45.5 or >60°C	<50 or >60°C

Feature	SYSTEM 1E Processor	SYSTEM 1 Processor(K875280)
Temperature range during a typical Liquid Chemical Sterilization Cycle	46 - 55°C	50 - 55°C
Sterilant Exposure Time	6 minutes	12 minutes
Rinse water preparation	Hot potable tap water is: • pre-filtered • flown through a UV Light treatment chamber to achieve ≥ a 6-log reduction of MS2 virus • Filtered through redundant 0.1 micron filter membranes	Hot potable tap water is: • pre-filtered • Filtered through 0.2 micron filter membrane
Number of rinses	2	4
Air Purge	Aids in removing excess water from instrument lumens after rinsing	
Water Filter Integrity Test	Conducted at the end of every liquid chemical sterilization s cycle and during the Diagnostic cycle	Conducted during the Diagnostic cycle only
Approximate Cycle time	25 minutes	30 minutes
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 sterilization processing cycle can not be performed until the problem is rectified and a successful Diagnostic cycle has been completed.	Performs 14 tests on processor's systems confirming proper function. Recommended to perform every 24 hours. After a failed Diagnostic cycle a liquid chemical sterilization processing cycle can not be performed until the problem is rectified and a successful Diagnostic cycle has been completed.
Accessories		
Sterilant	Uses S40 Sterilant Concentrate (see Table 5-2 for predicate comparison)	Uses STERIS 20 Sterilant
Processing Tray/Containers	Uses interchangeable processing trays/containers	
Quick Connects	Uses Quick Connects to adapt instrument lumens to the Tray/Container ports	
Operator Maintenance Requirements	Periodic replacement of printer tape, water filters and air filter	

Table 5-2. Sterilant Device Comparison Table

Feature	S40 Sterilant Concentrate	STERIS 20 STERILANT (K875280)	Sterilox Liquid Chemical HLD System (013280)
Indications for Use	S40 Sterilant Concentrate is for use only with the SYSTEM 1E Liquid Chemical Sterilant Processing System	STERIS 20 Sterilant Concentrate is for use only in the SYSTEM 1 Sterile Processing System	Sterilox is for use with manual or automated endoscope reprocessing protocols
Germicidal claim	Liquid Chemical Sterilant	Liquid Chemical Sterilant	High Level Disinfectant
Germicide Exposure Time (min) for intended use	6	12	10
Use Temperature	45.5-60°C – allowable 46-55°C - typical Potency and simulated use evaluations conducted at ≤43°C	50 - 60°C – allowable 50 – 55°C - typical	25°C
Reuse	Single use	Single use	Single use
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	Dispensed ready to use.
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 1 Processor.	Electrolytic generation of the active (mainly hypochlorous acid) from saline solution in the Sterilox Generator (*in situ*).

Feature	S40 Sterilant Concentrate	STERIS 20 STERILANT (K875280)	Sterilox Liquid Chemical HLD System (013280)
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]	Attacks surface and plasma membrane proteins impairing transport of solutes and the salt balance of bacterial cells[5].
Rinses	Automatic, UV-irradiated, dual 0.1 micron filtered, potable hot water.	Automatic, 0.2 micron filtered potable hot water.	Dependent upon use.
Microbial Efficacy			
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 situ*	Meets efficacy requirements[6]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*
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 situ*	Meets efficacy requirements[6]. *Bacillus subtilis* *Clostridium sporogenes* Testing conducted *in vitro*
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 situ*	Solution is fungicidal. *Trichophyton mentagrophytes* Testing conducted *in vitro*

[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] Pieterson et al., Water SA (1996) 22(1); 43-48.
[6] McDonnell et al., J. AOAC International (2000) 83:269-276.

Feature	S40 Sterilant Concentrate	STERIS 20 STERILANT (K875280)	Sterilox Liquid Chemical HLD System (013280)
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 situ*	Solution is bactericidal. *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* Testing conducted *in vitro*
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 2 Poliovirus Type 1 Influenza A Testing conducted *in situ*	Solution is virucidal. Herpes simplex Type 1 Poliovirus Type 2 Human immunodeficiciency virus Type I Testing conducted *in vitro*
Tuberculocidal Activity of Disinfectants AOAC Official Method 965.12	Not performed. A quantitative suspension Tuberculocidal test was conducted.	Solution is tuberculocidal. *Mycobacterium bovis* Testing conducted *in situ*	Solution is tuberculocidal. *Mycobacterium bovis* Testing conducted *in vitro*
Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal *Mycobacterium terrae* Testing conducted *in vitro*	Not performed. The AOAC Tuberculocidal Activity of Disinfectants was conducted.	Not performed. The AOAC Tuberculocidal Activity of Disinfectants was conducted.
Simulated-Use Test	Meets efficacy requirement. $\geq 6 \log^{10}$ reduction *Geobacillus stearothermophilus* spores	Meets efficacy requirement. $\geq 6 \log^{10}$ reduction *Bacillus subtilus* spores	Meets efficacy requirement $\geq 6 \log^{10}$ reduction of *Mycobacterium terrae*
Clinical In-Use	No surviving microorganisms on representative medical devices tested	Not required at time of submission.	No surviving microorganisms on the endoscopes tested.
Biocompatibility			
Cytotoxicity Device Extracts	Two rinses with UV treated, dual 0.1 micron membrane filtered water effectively reduces sterilant residues to safe levels.	Not performed	Not performed
Residue Reduction	Automatic within the	Automatic within	Effectively removed

Feature	S40 Sterilant Concentrate	STERIS 20 STERILANT (K875280)	Sterilox Liquid Chemical HLD System (013280)
	SYSTEM 1E Processor: Two rinses with UV treated, dual 0.1 micron membrane filtered water effectively reduces sterilant residues to safe levels.	SYSTEM 1 Processor: Four 0.2 micron filtered water rinses effectively reduce sterilant residues to safe levels.	from devices by the rinses following disinfection.
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 and their materials of construction, as established by testing materials and finished medical devices through 100 – 300 cycles. No device functional changes. Some materials show cosmetic changes such as fading of external markings but all remained legible, and bleaching of black anodized aluminum without harm to the base material.	Device components and materials were subjected to continuous immersion for unstated time periods. Does not produce any corrosion or other visible damage in the majority of endoscope components. Color changes and the "tack" of the coating of the outer endoscope sheaths were noted on some endoscopes. Corrosion was noted on anodized aluminum.

Conclusion

Based on the non-clinical and clinical tests described above, the SYSTEM 1E Processor and S40 Sterilant Concentrate demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR - 5 2010

Dr. Peter A. Burke
Senior Vice President
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K090036
Trade/Device Name: SYSTEM 1E Liquid Chemical Sterilant Processing System
Regulation Number: 21CFR 880.6885
Regulation Name: Liquid Chemical Sterilants / High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: March 16, 2010
Received: March 17, 2010

Dear Dr. Burke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K090036**

Device Name: **SYSTEM 1E Liquid Chemical Sterilant Processing System**

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 46 to 55°C, and rinses the load with extensively treated* potable water. The processed load should be used immediately.

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

* The extensive treatment of EPA potable water consists of:

1. Pre-filtration through two pre-filters:
   - Pre-filter 1 is a gross depth filter that removes approximately 5 micron or larger particles/contaminants.
   - Pre-filter 2 is a surface filter that removes particles/contaminants > 0.1 micron.
2. UV Irradiation:
   - During transit through the UV Water Treatment Chamber, a UV dose sufficient to achieve a ≥ 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.

Prescription Use _______ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090036

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