K131078

STERIS®

JUL 5 2013

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

STERIS Corporation
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Phone: (440) 354-2600
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Contact: Marcia L. Benedict
Senior Director, Regulatory Affairs
Tel: 440-392-7063
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Submission Date: June 11, 2013

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

SYSTEM 1E Liquid Chemical Sterilant Processing System (K090036, K101409, K102462, and K113520)

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 device was originally cleared under K090036. Following the initial clearance the FDA was notified of a second qualified supplier of an ultraviolet light water treatment subsystem providing equivalent water treatment performance, safety, and effectiveness to that described within K090036. This modification was subsequently cleared under K101409. Minor revisions to software that did not alter cycle parameters were cleared under K102462 and K113520.

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 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 SYSTEM 1E Quick Connects, if required, facilitate delivery of the liquid chemical sterilant use-solution and rinse water to internal channels.

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 Liquid Chemical Sterilant Processing System is the same as the predicate device except for the specific modifications described in this submission. The differences between the proposed and predicate devices are limited to the described modifications, and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

The following table summarizes the verification activities that were performed with their respective acceptance criteria to ensure that these limited hardware and software modifications do not affect the safety or effectiveness of the SYSTEM 1E Liquid Chemical Sterilant Processing System.

Test	Acceptance Criteria	Result
Biocompatibility testing	The described modifications to specific o-rings did not alter the biocompatibility profile of the device	Pass
SYSTEM 1E Processor Performance	The modifications do not affect the performance of the S1E Diagnostic and Liquid Chemical Sterilization Cycles	Pass
Software Verification Code Walk-Through	Only the targeted modifications were implemented to the device software	Pass
Software Validation	Only the targeted modifications were implemented to the device software	Pass
Machine Validation	The targeted modifications do not affect the performance of the device	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 5, 2013

STERIS Corporation
Ms. Marcia L. Benedict
Senior Director, Regulatory Affairs
5960 Heisley Road
Mentor OH 44060

Re: K131078
Trade/Device Name: SYSTEM 1E Liquid Chemical Sterilant Processing System
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: June 11, 2013
Received: June 12, 2013

Dear Ms. Benedict:

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.

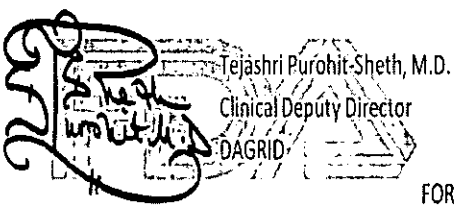
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131078

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

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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)

Elizabeth F. Claverie -S
2013.06.28 21:56:22 -04'00'

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

510(k) Number: K131078