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STERIS®

SEP 21 2010

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

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Contact: Robert Sullivan
Senior Director, FDA Regulatory Affairs
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Submission Date: August 26, 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

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

## 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 this 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.

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 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 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 Liquid Chemical Sterilant Processing System is the same as the predicate K090036 and K101409 except for modifications to the device software. These modifications are intended to update the software printouts to match the cleared device configuration and enhance the device performance. The differences between the proposed and predicate device are limited to the described modifications of the device software 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. The test results verified that the software revision meets the software requirements and test acceptance criteria thereby ensuring that the software modifications do not affect the safety or effectiveness of the SYSTEM 1E Liquid Chemical Sterilant Processing System.

| Test | Acceptance Criteria | Result |
|---|---|---|
| Software Verification /Code Walk-Through | Only targeted modifications were implemented to the device software | Pass |
| Software Validation | Only targeted modifications were implemented to the device software | Pass |
| Machine Validation | 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Sullivan
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SEP 21 2010

Re: K102462
Trade/Device Name: SYSTEM 1E 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: August 26, 2010
Received: August 27, 2010

Dear Mr. Sullivan:

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

SEP 2 1 2010

510(k) Number (if known): K102462

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   - 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.

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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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K102462