K013280

1 510(k) Summary

SEP 1 8 2002

1.1 Date of Summary Preparation: Wednesday, September 18, 2002

1.2 Manufacturers Contact Person:

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1.3 Trade Name: Sterilox Liquid Chemical High Level Disinfectant System

1.4 Classification Name, Product Code, Class, Classification Reference:

Classification Name	Product Code	Class	21CFR §
High Level Disinfectant	MED	II	880.6885

1.5 Special Controls:

Guidance on the Content and Format of Pre-market Notification [510(k)] Submissions for Liquid Chemical Sterilant/ High Level Disinfectants; user information and training.

1.6 Indications for Use:

Sterilox is a high level disinfectant system intended for processing heat-sensitive medical devices when used according to the User Manual with an immersion time of ten (10) minutes at 25°C. Sterilox is a single use product generated on site for use at its MRC of 650-675 ppm (AFC). Sterilox is intended for use with manual or automatic endoscope reprocessing protocols.

Sterilox High Level Disinfectant system is intended for use by qualified health care personnel trained in its use.

1.7 Device Description:

The Sterilox Liquid Chemical High Level Disinfectant System is an apparatus that produces a single use High Level Disinfectant by on-site electrochemical activation (electrolysis) of a dilute aqueous solution of sodium chloride (NaCl). The germicide is then circulated through and about reusable heat-sensitive medical devices either in a manual system or within a typical washer-disinfector used in hospitals, clinics and various other health care settings. It is a device intended for use by qualified healthcare personnel trained in its use.

The Sterilox device is similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

1.8 Substantially Equivalent Commercially Available Devices:

The Sterilox Liquid Chemical High Level Disinfectant System is substantially equivalent to the products described herein with respect to indications for use, device design, materials, and method of manufacture. Section 4 and Appendix A contains all relevant and available information for the following commercially available predicate devices:

Cidex liquid chemical sterilants/disinfectants ~ (K923744, K924334, K924434)
Endo-Spor Plus/Hyprocide Liquid Chemical Sterilants ~ (K972708)
Steris 20™ Sterilant/Steris System 1™ Processor ~ (K875280)

These predicate devices are commercially available and marketed Unclassified and Class II devices indicated for use as liquid chemical sterilants/high level disinfectants.

1.9 Substantial Equivalence Comparison:

The Sterilox Liquid Chemical High Level Disinfectant System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

1.9.1 General:

	Sterilox Liquid Chemical High Level Disinfectant System *(System and Germicide)*	**Steris** *(System and Germicide)*	**Endo-Spor Plus/Hyprocide** *(Germicide)*	**Cidex** *(Germicide)*
Labeling	High Level Disinfectant	Liquid Chemical sterilant	Liquid Chemical Sterilant/High Level Disinfectant	Liquid Chemical Sterilant/High Level Disinfectant
Intended Use	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body Intended for use by qualified healthcare personnel trained in its use.	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body Intended for use by qualified healthcare personnel trained in its use.	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body Intended for use by qualified healthcare personnel trained in its use.	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body Intended for use by qualified healthcare personnel trained in its use.

	Sterilox Liquid Chemical High Level Disinfectant System *(System and Germicide)*	Steris *(System and Germicide)*	Endo-Spor Plus/Hyprocide *(Germicide)*	Cidex *(Germicide)*
Human Factors	Dispensed ready to use	Dispensed ready to use	Dispensed ready to use	Needs activation
Design, Construction, Components	Aqueous solution Used in a standalone container or Washer/Disinfector	Aqueous solution Must be used in a dedicated sterile processing system	Aqueous solution Used in a standalone container or Washer/Disinfector	Aqueous solution Used in a standalone container or Washer/Disinfector
Process Monitors	Pre-programmed colorimeter for direct-reading of chlorine concentration	Chemical reaction on indicator pad to produce color change	None	Chemical Indicator Chemical reaction on indicator pad to produce color change
Reuse	Single use	Single use	14 days	14 days
Software Controls	Yes	Yes	N/A	N/A
Process Parameters				
Liquid Chemical Sterilant	N/A	12 min at 50-56°C	180 min at 20°C	10 hr at 25°C
High Level Disinfectant	10 min at 25°C	N/A	15 min at 20°C	45 min at 25°C

1.9.2 Operational Principles:

The basic operational principles of the Sterilox Liquid Chemical High Level Disinfectant System and the predicate devices are similar in that they result in high level disinfection of reusable medical equipment that is heat sensitive by putting their germicides in contact with the devices for a specified period of time and temperature, in either static or dynamic conditions. The operating principles are compared as follows:

	Sterilox Liquid Chemical High Level Disinfectant System *(System and Germicide)*	Steris *(System and Germicide)*	Endo-Spor Plus/Hyprocide *(Germicide)*	Cidex *(Germicide)*
Form	Inputs of water & germicide	Inputs of water & germicide	germicide	germicide
Control	Software controlled	Software controlled	N/A	N/A

	Sterilox Liquid Chemical High Level Disinfectant System *(System and Germicide)*	**Steris** *(System and Germicide)*	**Endo-Spor Plus/Hyprocide** *(Germicide)*	**Cidex** *(Germicide)*
Contact	Liquid contact	Liquid contact	Liquid contact	Liquid contact
Purpose	To achieve high level disinfection by destroying viable forms of microbial life, when used according to labeling	To achieve liquid chemical sterilization by destroying viable forms of microbial life, when used according to labeling	To achieve liquid chemical sterilization or high level disinfection by destroying viable forms of microbial life, when used according to labeling	To achieve liquid chemical sterilization or high level disinfection by destroying viable forms of microbial life, when used according to labeling
Mode of Action	Sterilox exerts its germicidal effect by attacking the surface and plasma membrane proteins, impairing transport of solutes and the salt balance of bacterial cells (Pieterson *et al*, Water SA (1996) **22**(1); 43-48)	It is believed that peracetic acid exerts its germicidal effect by oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls (Block, 1991)	It is believed that hydrogen peroxide and peracetic acid exert their germicidal effect by oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls (Block, 1991)	Strong interaction with outer cell layers; cross linking of amino groups in proteins and inhibition of transport processes into cell (McDonell, *Clin. Microbiol. Rev.*, 1999 147-179)

Comment: Mark to write mode of action for other germicides

The parameters that are measured and displayed are generally the same as those for the predicate devices

1.10 Indications and Contraindications:

Relative indications and contraindications for the Sterilox Liquid Chemical High Level Disinfectant System and commercially available devices for similar intended uses are the same.

1.11 Microbiological Efficacy:

The Sterilox germicide is a single use solution and all efficacy testing was conducted at the MRC of 650 ppm AFC.

Test Method	Test Organisms	Results
Sporicidal Activity of Disinfectants; AOAC Official Method 966.04	*Bacillus subtilis* *Clostridium sporogenes*	Meets liquid chemical Sterilant efficacy requirements[3]
Confirmatory Sporicidal Activity of Disinfectants; AOAC Official Method 966.04	*Bacillus subtilis* *Clostridium sporogenes*	Meets liquid chemical Sterilant efficacy requirements[3]
Fungicidal Activity of Disinfectants (AOAC 6.3.02:1995, Official Method 955.17)	*Trichophyton mentagrophytes*	Solution is fungicidal
Use-Dilution Method (AOAC 6.2.01:1995, Official Methods 955.14, 955.15, 964.02)	*Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa*	Solution is bactericidal
EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	*Herpes Simplex I* *Poliovirus II* *Human Immunodeficiency Virus Type I*	Solution is virucidal
Quantitative Tuberculocidal Test	*Mycbacterium bovis*	Solution is tuberculocidal
Simulated Use Test	*Bacillus subtilis*[1] *Clostridium sporogenes*[1] *Mycobacterium terrae*[2]	Meets efficacy requirements
Clinical In-Use	Organisms remaining on flexible endoscopes after clinical use	No surviving microorganisms on any of the endoscopes tested.

[1]Simulated use testing was conducted using actual used flexible fiber optic endoscopes whose external surfaces and internal channels were contaminated with $>10^6$cfu *Bacillus subtilis* and *Clostridium sporogenes* spores. The inoculated scopes were processed in Sterilox manually for 30 minutes at 25° C.
[2]Simulated use testing was conducted using actual used flexible fiberoptic endoscopes whose external surfaces and internal channels were contaminated with $>10^6$cfu *Mycobacterium terrae*. The inoculated scopes were processed in Sterilox manually for 10 minutes at 25° C.
[3]This testing was conducted in accordance with AOAC Offficial Method 966.04, except that polyester loops (instead of silk loops) were used as a carrier.

1.12 Residue Data:

Residue testing was performed to quantify any residuals remaining after disinfection with Sterilox above MRC and rinsing according to the label claims. The endoscope was then extracted and the eluates analyzed for residual Sterilox components. The results showed that Sterilox germicide well above its maximum use concentration is effectively removed from a complex device such as a flexible endoscope by the rinse cycle after disinfection and therefore poses no additional risk to the patient or user of the device.

1.13 Toxicological Evaluation of Sterilox:

Testing was performed to determine the potential toxicological effects of exposure to Sterilox liquid chemical High Level Disinfectant. The results are summarized as follows:

Skin Irritation (Rabbits)	Non-irritating
Skin Sensitization (Guinea Pig)	Non-sensitizing
Acute Dermal Toxicity (Rabbits)	Dermal LD_{50} > 2 g/kg body weight
Acute Oral Toxicity (Rats)	Dermal LD_{50} > 5 g/kg body weight
Primary Eye Irritation (Rabbits)	Non-irritating
Bacterial Mutation Assay	Non-mutagenic

In section III.I.3 'Evaluation of toxicity' of the guidance for industry and FDA reviewers indicates the tests that should be considered when evaluation the biocompatibility of the germicidal product or the individual ingredients.

1.14 Patient toxicity:

Skin irritation and skin sensitization maximization test have been conducted on the product, Sterilox germicide. The test reports indicate that the studies were conducted properly. There were no indications of irritation or sensitization. Although positive results of studies on cytotoxicity and on haemocompatibility might be predicted from knowledge of the effects of hypotonic aqueous solutions generally, these results would also be expected of any suitably disinfected water used to rinse equipment.

As the toxicity of the product is essentially similar to that of chlorine based disinfectants, it is unlikely that any useful information will be obtained from further studies and it is therefore undesirable on the grounds of animal welfare to conduct these studies.

1.15 User toxicity:

An acute oral toxicity test (by the OECD 'fixed dose' procedure), a primary eye irritancy study and a bacterial mutagenicity study in *Salmonella typhimurium* (the 'Ames' test) have been conducted on the product, Sterilox germicide. The test reports indicate that the studies were conducted properly. The results of these tests indicated that Sterilox germicide is non-mutagenic and non-irritating to the eye.

As, for toxicological purposes, the product is essentially equivalent to chlorine disinfectant, the conclusion reached by the International Program on Chemical Safety in Environmental Health Criteria 216 (2000) concerning the toxic effects of these disinfectants in drinking water that:

"Evidence from animal and human studies suggests that exposure to chlorine, chlorite solutions, chloramine and chlorine dioxide themselves probably do not contribute to the development of cancer or any toxic effects".

This also applies to the Sterilox germicide solution, thus undertaking additional testing is scientifically unnecessary and, on animal welfare grounds the studies should be omitted.

1.16 Toxicological Conclusion:

For all practical purposes the health risks to patient and to operator arising from exposure to Sterilox germicide and diluted Sterilox germicide are minimal. The principal potential effect of the chemicals present in Sterilox would be irritation, but Sterilox does not exhibit this effect in tests. Sterilox is unlikely to pose a significant risk to either patient or user.

1.17 Materials Compatibility:

The material compatibility of the Sterilox germicide was evaluated by subjecting a variety of metallic, plastic, adhesive and rubber endoscope components to continuous immersion in Sterilox. The samples were inspected for, visible change, visible evidence of damage or any other change in appearance. Sterilox germicide 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. Refer to User Manual for materials compatibility information.

1.18 Assessment of non-clinical performance data for equivalence:

Currently there are no FDA standards for this device. However, the Sterilox Liquid Chemical High Level Disinfectant System complies with:

The Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC and is manufactured under a Quality System approved by LRQA (Notified Body No. 0088) complying with Annex VII & V of the Directive.

The Sterilox Liquid Chemical High Level Disinfectant System intends to comply with the FDA guidance document "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants," dated January 3, 2000, where applicable.

1.19 Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Sterilox Technologies concludes that the new device, the Sterilox Liquid Chemical High Level Disinfectant System, is safe, effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2002

Sterilox Technologies, Incorporated
C/O Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K013280
Trade/Device Name: Sterilox Liquid Chemical High Level Disinfectant System
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: September 5, 2002
Received: September 6, 2002

Dear Mr. Mosenkis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name : Sterilox Liquid High Level Disinfectant System

Indications for Use:

Sterilox is a high level disinfectant system intended for processing heat-sensitive medical devices when used according to the User Manual with an immersion time of ten (10) minutes at 25°C. Sterilox is a single use product generated on site for use at its MRC of 650-675 ppm (AFC). Sterilox is intended for use with manual or automatic endoscope reprocessing protocols.

This device is intended for use by qualified healthcare personnel trained in its use.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K013280

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

Concurrence of CDRH, Office of Device Evaluation (ODE)