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TSO

K020875 TSO_3-125L Ozone Sterilizer

510(k) Summary

Applicant's Name and Address
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Submission Date
March 15th 2002

Trade Name
TSO_3 Ozone Sterilizer, model *125L*

Common Name
TSO_3-*125L* Ozone Sterilizer

Classification Name
Sterilizer, Chemical
Class II (as per 21CFR, part 880.6860 equivalent device)

Legally Marketed Equivalent Device Name(s)
STERRAD® 100S Sterilization System

Description of Device

TSO_3 model *125L* Ozone Sterilizer is intended to sterilize reusable medical devices that have been previously cleaned. Ozone is generated within the sterilizer to provide an efficient sterilant without the concerns for transporting, handling and disposing of toxic chemicals. The sterilization chamber has a capacity of 125 liters (4 cu. ft.). It requires medical grade oxygen, water and electricity.

The Model *125L* is equipped with a unique factory-programmed control system for processing reusable medical devices.

Processed medical instruments requires no aeration time at the end of the sterilization cycle.

The TSO_3 sterilization pouch and anodized aluminum sterilization containers are used as packaging for medical devices to be sterilized.

The TSO_3 **OZO-TEST™** self-contained Biological Indicator *(B. stearothermophilus)* is recommended for use in evaluating cycle performance. TSO_3 Chemical Indicator is recommended for use to differentiate between processed and unprocessed loads and to indicate that the load has been exposed to the sterilization process.

Model *125L* could be installed as a free standing unit or recessed behind a wall.

No exhaust gas ventilation duct is required in a room that is adequately ventilated.

Effectiveness

Model *125L* Validation testing was performed using the « overkill » approach to demonstrate the effectiveness of the process.

This process has been demonstrated to be effective on medical devices packaged in the TSO_3 sterilization pouch and in rigid anodized aluminum sterilization containers using disposable cellulose filter paper.

Safety

Model *125L* sterilizer have been designed, constructed and tested to meet the safety and performance requirements of various North American safety codes and standards. The TSO3-*125L* sterilizer complies with the applicable portions of the following standards:

- Canadian Standard Association (CSA) Standard C22.2 No 1010.1
- Underwriters Laboratory Standard UL 61010A-1
- Federal Communication Commission (FCC) Part 18 / EN 55011
- International Electrotechnical Commisssion (IEC) Standard IEC 60601-1-2

A Fault Tree Analysis and Mitigation (FTA-MIT) and a Failure Mode Effects and Criticality Analysis (FMECA) has been conducted on the Model *125L* entire system to ensure safety features and control redundancies has been implemented in the design and will be maintained during the manufacturing, installation, maintenance and servicing of the sterilizers.

To ensure optimum performance, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the instrument manufacturer's instructions are followed, and that each sterilization load is monitored with biological and chemical sterilization process indicators.

The software controls of the Model *125L* have been designed providing safeguards that only intended operating cycles function to completion. An unintended condition will abort the cycle and provide appropriate information identifying the source of the condition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Technologies of Sterilization with Oxone, TSO3 Incorporation
C/O Charles O. Hancock, RAC
President
Charles O. Hancock Associates, Incorporated
33 Black Watch Trail
Fairport, New York 14450-3701

Re: K020875
Trade/Device Name: TSO_3 Ozone Sterilizer, Model 125lL
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF, FRC
Dated: June 11, 2003
Received: June 13, 2003

Dear Mr. Hancock:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

The TSO_3-Model *125L* is an Ozone Sterilizer intended for use in the sterilization processing of reusable medical devices in Health Care Facilities. The TSO_3 Model *125L* Ozone Sterilizer is designed for sterilization of both metal and non-metal medical devices at low temperatures. The sterilization cycle operates at very low pressure and low temperatures, consequently it is suitable for processing medical devices sensitive to heat and moisture.

The TSO_3-*125L* Ozone Sterilizer is designed to sterilize instruments and devices with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

The TSO_3-*125L* Ozone Sterilizer is also designed to process medical devices having a single stainless steel lumen with:
- an inside diameter of 2 mm or larger and a length of 250 mm or shorter;
- an inside diameter of 3 mm or larger and a length of 470 mm or shorter;
- an inside diameter of 4 mm or larger and a length of 600 mm or shorter.

Note: Testing conducted employing half cycle with a SAL of 10^{-6} with no survivors.

The packaging compatible with the TSO_3-Model *125L* Ozone Sterilizer are TSO_3 sterilization pouch and rigid anodized aluminum containers using disposable cellulose filter paper.

Chin S. Lim

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

510(k) Number: K020875