K051595

TSO

EXTENDED LUMEN CLAIMS FOR
TSO_3 OZONE STERILIZER, MODEL *125L*

510(k) Summary

JUL 26 2006

Applicant's Name and Address
TSO_3 Inc.
2505, Dalton Avenue
Ste-Foy, Quebec, Canada G1P 3S5

Contact Person, Telephone, FAX
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U.S. Agent
Charles O. Hancock Inc.
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Submission Date
June 14, 2005

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)
TSO_3 Ozone Sterilizer, model *125L* (K020875)

Description of Device

TSO$_3$ Ozone Sterilizer, model *125L* is intended to sterilize medical devices that has been previously cleaned.

The sterilization chamber has a capacity of 125 liters (4.3 cu. ft.).

It requires USP grade oxygen, water and electricity. Model *125L* could be installed as a free standing unit or recessed behind the wall. No exhaust gas ventilation duct is required as long as the room is adequately ventilated. By-products are oxygen and low humidity water vapor.

Model *125L* is equipped with a unique factory-programmed control system.

Non-woven wrapping material or pouches and anodized aluminum containers are used as packaging for medical devices to be sterilized.

OZO-TEST® self-contained Biological Indicators *(B. stearothermophilus)* are recommended for use in evaluating cycle performance.

TSO$_3$ Chemical Indicators are available for this process.

No aeration is needed following the sterilization cycle. The sterilized items are cool to the touch and can be removed immediately and used, or stored for future use.

Effectiveness

Model *125L* validation testing for extended lumen claims was performed using the « overkill » approach to demonstrate the effectiveness of the process.

Safety

Safety of the TSO$_3$ Ozone Sterilizer, model *125L* was demonstrated into the original 510(k) submission (K020875). The content of the actual submittal does not compromise the safety of the device.

TSO_3 Ozone Sterilizer, Model *125L*, has the ability to sterilize successfully medical devices having a single stainless steel lumen which falls into the following length and internal diameters*:

Internal diameter (mm)	Internal diameter (French) (Approximative correspondence)	Length (mm)
0.9	2.7	485
1	3	500
2	6	575
3	9	650
4	12	700

*Note: Testing on lumens were conducted employing half cycle to demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

TSO_3, Incorporated
C/O Mr. Charles O. Hancock
Charles O. Hancock Associates, Incorporated
33 Black Watch Trail
Fairport, New York 14450

Re: K051595
Trade/Device Name: TSO_3 Ozone Sterilizer, Model 125L
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF
Dated: July 10, 2006
Received: July 10, 2006

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.

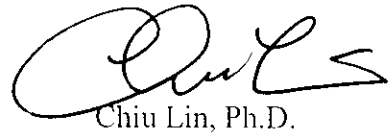
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K051595

Device Name: TSO_3 Ozone Sterilizer, Model 125L

Indications For 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 Ozone Sterilizer, Model *125L*, 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 temperature, consequently it is suitable for processing medical devices sensitive to heat and moisture.

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

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)

Sign-Off)
of Anesthesiology, General Hospital,
Control, Dental Devices
Number: K051595