510(k) Summary K071385

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products
Division of Ethicon, Inc.
33 Technology Drive
Irvine, CA 92618

NOV 2 9 2007

Contact Person
Reuben Lawson
Regulatory Affairs Manager
Tel: (949) 789-8545
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May 15, 2007

1.0 CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Sterilizer, Class II
Common/Usual Name: Hydrogen Peroxide Gas Plasma Sterilization System
Product Classification: Sterilizer, Class II
Proprietary Name: STERRAD® 100NX™ Sterilizer

2.0 PREDICATE DEVICES

STERRAD® NX® Sterilization System [K042116]

3.0 INDICATIONS FOR USE

The STERRAD 100NX™ Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD® sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization.

The STERRAD® 100NX™ Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with the following materials and dimensions can be processed in the STERRAD® 100NX™ Sterilizer **Standard cycle:**

- Single channel stainless steel lumens with an inside diameter of 0.7mm or larger and a length of 500mm or shorter*

Flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD® 100NX™ Sterilizer **Flex Scope cycle:**

- Single channel flexible endoscope with a polyethylene or Teflon (polytetrafluoroethylene) lumen with an inside diameter of 1mm or larger and length of 850mm or shorter**

Note: With the exception of the 1 x 850 mm flexible endoscopes, the validation studies were performed using a validation load consisting of two instrument trays each weighing 10.7 lbs. The 1 x 850 mm flexible endoscopes were validated without any additional load.

* A maximum of ten lumens, five per tray per sterilization cycle.
** A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load.

4.0 DESCRIPTION OF DEVICE

The STERRAD® 100NX™ Sterilizer is a self-contained stand-alone system of hardware and software designed to sterilize medical instruments and devices using a patented hydrogen peroxide gas plasma process. Hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide into the vaporizer where the solution is heated and vaporized, introducing the vapor into the chamber under sub-ambient pressure and transforming the vapor into a gas-plasma using electrical energy. The STERRAD® 100NX™ Sterilizer has two different sterilization cycles, the Standard cycle and the Flex cycle.

The hardware for the STERRAD® 100NX™ Sterilizer consists of a sterilization chamber and a variety of instruments and components which are housed in a covered frame. The sterilizer system also uses accessories such as a disposable sterilant cassette, reusable instrument trays, printer paper, and an optional movable cart. The STERRAD® 100NX™ Sterilizer can be placed directly on a table, counter top, or on the movable cart.

5.0 SUMMARY OF NONCLINICAL TESTS

5.1 Validation Testing

Testing was performed using the "overkill" approach utilizing *G. stearothermophilus* spores. Table 8-1 on the following page identifies the validation studies performed and the results obtained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Mr. Reuben Lawson
Regulatory Affairs Manager
Advanced Sterilization Products, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K071385
Trade/Device Name: STERRAD 100NX
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: November 12, 2007
Received: November 13, 2007

Dear Mr. Lawson:

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.

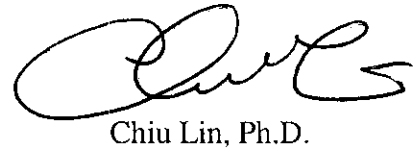
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K071385
Device Name: STERRAD 100NX
Indications for Use:

The STERRAD® 100NX™ Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization.

The STERRAD® 100NX™ Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with the following materials and dimensions can be processed in the STERRAD 100NX™ Sterilizer **Standard cycle:**

> Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter.*

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD® 100NX™ Sterilizer **Flex Scope cycle:**

> Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 850 mm or shorter.**

Note: With the exception of the 1 x 850 mm flexible endoscopes, the validation studies were performed using a validation load consisting of two instrument trays each weighing 10.7 lbs. The 1 x 850 mm flexible endoscopes were validated without any additional load.

*A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle.
** A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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