K042116

APR 22 2005

510(k) Summary

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

Contact Person
Natalie Bennington
Regulatory Affairs Project Manager
Tel: (949) 453-6482
Fax: (949) 789-3900

April 1, 2005

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® NX Sterilizer

2.0 PREDICATE DEVICES

STERRAD® 50, 100S and 200 Sterilization Systems

3.0 INDICATIONS FOR USE

The STERRAD® NX 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® NX 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® NX Sterilizer **Standard cycle:**

Single channel stainless steel lumens with

- An inside diameter of 1 mm or larger and a length of 150 mm or shorter†
- An inside diameter of 2 mm or larger and a length of 400 mm or shorter†

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

Single channel stainless steel lumens with

- An inside diameter of 1 mm or larger and a length of 500 mm or shorter†

Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope with

- An inside diameter of 1 mm or larger and length of 850 mm or shorter*

† The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

*Only one flexible endoscope can be processed per sterilization cycle with or without a silicone mat. No additional load.

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

4.0 DESCRIPTION OF DEVICE

The STERRAD® NX 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® NX Sterilizer has two different sterilization cycles, the Standard cycle and the Advanced cycle.

The hardware for the STERRAD® NX 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® NX 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.

Table 8-1: Validation Studies

Study	Results
Dose Response with 1 x 500mm Stainless Steel Lumens	Passed
Surface Sterilization	Passed
Mated Surface Sterilization	Passed
1 x 500mm Stainless Steel Lumen Validation	Passed
1 x 150 Stainless Steel Lumen Validation	Passed
2 x 400mm Stainless Steel Lumen Validation	Passed
1 x 850mm Flexible Endoscope Validation	Passed
Pouched 1 x 500mm Stainless Steel Lumen Validation	Passed
Bacteriostasis Testing in Standard and Advanced Cycles	Passed
Sporicidal Testing	Passed
In Use Testing	Passed
Bacteriostasis/Fungistasis Testing	Passed
Simulated Use Testing	Passed
Toxicity Testing of Materials	Passed
Chemical Indicator Functionality	Passed
Biological Indicator Functionality	Passed
Bacteriostasis Testing of CycleSure Biological Indicator	Passed
Device Functionality and Material Compatibility	Passed
Process Reproducibility	Passed

6.0 OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the STERRAD® NX Sterilizer is safe and effective for sterilization of medical devices within the indications for use for the sterilizer and establish equivalence of the STERRAD® NX Sterilizer to the predicate devices, the STERRAD® 50, 100S and 200 Sterilizers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2005

Advanced Sterilization Products
Ms. Natalie Bennington
Regulatory Affairs Project Manager
ETHICON, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K042116
Trade/Device Name: STERRAD® NX Sterilizer
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: April 1, 2005
Received: April 4, 2005

Dear Ms. Bennington:

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 (301) 443-6597 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): K042116

Device Name: STERRAD® NX Sterilizer

Indications-For-Use:
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Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(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)

Sheila A. Murphy for KP

ision Sign-Off)
ivision of Anesthesiology, General Hospital,
nfection Control, Dental Devices

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