AUG 18 2003

510(k) Summary

K030429

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

Contact Person
Kevin Corrigan
Director of Regulatory Affairs
Tel: (949) 453-6410
Fax: (949) 789-3900

August 12, 2003

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® 200 Sterilizer

2.0 PREDICATE DEVICES

STERRAD® 100S Sterilization System

3.0 INDICATIONS FOR USE

The STERRAD® 200 Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.

The STERRAD® 200 Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with only a single stainless steel lumen with the following dimensions can be processed in the STERRAD® 200 Sterilizer.

- An inside diameter of 1 mm or larger and a length of 125 mm or shorter*
- 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 400 mm or shorter

Teflon® and polyethylene lumen instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD® 200 Sterilizer.

*The validation testing for this lumen size was conducted using a maximum of 12 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

Note: The validation studies for this sterilizer were performed using the STERRAD cycle consisting of a 6-minute 45-second injection phase followed by a 2-minute diffusion phase and a 2-minute plasma phase. The validation studies were performed using a validation load consisting of four instrument trays each weighing 9.12 lbs. (the total weight of the load was 36.48 lbs).

4.0 DESCRIPTION OF DEVICE

The STERRAD® 200 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 bowl where the solution is heated and transformed into a vapor, introducing the vapor into the process chamber under negative pressure and transforming the vapor into a gas plasma with electrical energy.

The equipment (hardware) for the STERRAD® 200 Sterilizer is the same as that of the predicate device, the STERRAD® 100S Sterilizer. (Note: The STERRAD® 200 Sterilizer is available in either a one-door or two-door model, depending on customer preference). The hardware consists of a sterilization chamber onto which is mounted a variety of instruments and components, housed in a covered frame. The system also uses accessories such as a movable carriage for transport of the cart, disposable sterilant cassettes, reusable instrument trays, printer paper and ink cartridges.

5.0 SUMMARY OF NONCLINICAL TESTS

5.1 Validation Testing

Testing was performed using the "overkill" approach utilizing *B. stearothermophilus* spores. Table one on the following page identifies the validation studies performed and the results obtained.

Table 1: Validation Studies

Study	Results
Dose Response with 1 x 125mm Lumens	Passed
Dose Response with 2 x 250mm Lumens	Passed
Dose Response with 3 x 400mm Lumens	Passed
Surface Sterilization	Passed
Mated Surface Sterilization	Passed
1 x 125mm Lumen Validation	Passed
2 x 250mm Lumen Validation	Passed
3 x 400mm Lumen Validation	Passed
6 x 310mm Lumen Validation	Passed
Pouched 1 x 125mm Lumen Validation	Passed
Pouched 2 x 250mm Lumen Validation	Passed
Pouched 3 x 400mm Lumen Validation	Passed
Bacteriostasis Testing of Carrier Materials	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
Bacteriostasis Testing of CycleSure Biological Indicator	Passed

6.0 OVERALL PERFORMANCE CONCLUSIONS

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2003

Ms. Natalie Bennington
Senior Regulatory Affairs Specialist
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

Re: K030429
Trade/Device Name: STERRAD® 200 Sterilizer
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF, MRL
Dated: May 21, 2003
Received: May 22, 2003

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 (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,

Patricia Cusenta /for

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

Enclosure

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

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

510(k) Number: K030429

510(k) Number (if known): K030429

Device Name: STERRAD® 200 Sterilizer

Indications-For-Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)