K023290 APR - 3 2003

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products
Division of Ethicon, Inc.
33 Technology Drive
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March 24, 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® 50 Sterilization System and STERRAD® 100S Sterilization System

2.0 PREDICATE DEVICES

STERRAD® 50 Sterilization System (K981625) and STERRAD® 100S Sterilization System (K991999)

3.0 INDICATIONS FOR USE

This Premarket Notification is to expand the Indications for Use for the STERRAD 50 Sterilizer (K981625) and the STERRAD 100S Sterilizer (K991999) to include titanium as a compatible material and to expand the lumen sizes to include medical devices with only a single stainless steel lumen in the following configurations:

- 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

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

For information pertaining to previously cleared materials and lumen sizes, please reference K981625 and K991999.

4.0 DESCRIPTION OF DEVICES

The STERRAD® 50 & 100S Sterilizers are self-contained stand-alone systems 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 radio frequency (RF) electrical energy.

The equipment (hardware and software) for the STERRAD® 50 & 100S Sterilizers is the same as that of the predicate devices. 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 disposable sterilant cassettes, reusable instrument trays, printer paper and ink cartridges.

5.0 SUMMARY OF NONCLINICAL TESTS

5.1 STERRAD® 50 & 100S Validation

5.1.1 Testing was performed using the "overkill" approach.

5.1.2 Test Organism: *B. stearothermophilus*

5.1.3 Titanium Surface Sterilization

5.1.3.1 STERRAD® 50

Surface sterilization efficacy studies were performed in the STERRAD® 50 Sterilizer with titanium materials representative of the materials commonly used in re-usable medical devices.

Results of this study demonstrated an SAL of at least 10^{-6} for medical device surface sterilization in the complete STERRAD® 50 sterilization process titanium material listed as recommended for use in the STERRAD® 50 Sterilizer.

5.1.3.2 STERRAD® 100S

Surface sterilization efficacy studies were performed in the STERRAD® 100S Sterilizer with titanium materials representative of the materials commonly used in re-usable medical devices.

Results of this study demonstrated an SAL of at least 10^{-6} for medical device surface sterilization in the complete STERRAD® 100S sterilization process titanium material listed as recommended for use in the STERRAD® 100S Sterilizer.

5.1.4 Lumen Sterilization

5.1.4.1 STERRAD® 50

Half-cycle validation tests were performed using *B. stearothermophilus* endospores (>10^6 spores) inside stainless steel

lumens, 1 mm internal diameter (ID) x 125 mm long and 2 mm (ID) x 250 mm long, placed within the STERRAD® 50 Sterilizer expanded utility validation load.

The results of this study demonstrated that a sterility assurance level (SAL) of 10^{-6} is achieved in a full STERRAD 50 Sterilization cycle when processing stainless steel lumens of ≥1 mm (ID) x ≤125 mm long and ≥2 mm (ID) x ≤250 mm long.

5.1.4.2 STERRAD® 100S

Half-cycle validation tests were performed using *B. stearothermophilus* endospores (>10^6 spores) inside stainless steel lumens, 1 mm internal diameter (ID) x 125 mm long and 2 mm (ID) x 250 mm long, placed within the STERRAD® 100S Sterilizer expanded utility validation load.

The results of this study demonstrated that a sterility assurance level (SAL) of 10^{-6} is achieved in a full STERRAD 100S Sterilization cycle when processing stainless steel lumens of ≥1 mm (ID) x ≤125 mm long and ≥2 mm (ID) x ≤250 mm long.

5.1.5 Tyvek-Mylar Pouched Device Sterilization

5.1.5.1 STERRAD® 50

Half-cycle validation studies with 1 mm internal diameter (ID) x 125 mm long and 2 mm (ID) x 250 mm long stainless steel straight lumens in Tyvek-Mylar pouches were performed to demonstrate sterilization efficacy with the STERRAD® 50 Sterilization System.

The results of this study demonstrated that a sterility assurance level (SAL) of 10^{-6} was achieved in a full STERRAD 50 Sterilization cycle when processing stainless steel lumens, ≥1 mm (ID) x ≤125 mm long and ≥2 mm (ID) x ≤250 mm long, packaged in STERRAD Sterilization pouches. This study validates the use of STERRAD Sterilization pouches in the STERRAD 50 Sterilization System.

5.1.5.2 STERRAD® 100S

Half-cycle validation studies with 1 mm internal diameter (ID) x 125 mm long and 2 mm (ID) x 250 mm long stainless steel straight lumens in Tyvek-Mylar pouches were performed to demonstrate sterilization efficacy with the STERRAD® 100S Sterilization System.

The results of this study demonstrated that a sterility assurance level (SAL) of 10^{-6} was achieved in a full STERRAD 100S Sterilization cycle when processing stainless steel lumens, ≥1 mm

(ID) x ≤125 mm long and ≥2 mm (ID) x ≤250 mm long, packaged in STERRAD Sterilization pouches. This study validates the use of STERRAD Sterilization pouches in the STERRAD 100S Sterilization System.

5.2 Supporting Microbiological Testing

5.2.1 Simulated Use Testing

5.2.1.1 STERRAD 50

The devices were inoculated with spores of *B. stearothermophilus* suspended in 300 ppm hard water (AOAC preparation) supplemented with 5% fetal bovine serum. After drying, the devices were treated either by cleaning, then processing in the STERRAD® 50 sterilizer or by directly processing in the sterilizer, i.e., without cleaning.

The results show that the STERRAD® 50 process is not affected by the presence of an organic and inorganic challenge. The SLR for the unwashed, processed devices was 6.1 and for the washed, processed devices it was 6.0 (1 mm x 125 mm in length devices). The SLR for both the washed and unwashed, processed devices was 6.9 (2 mm ID x 250 mm in length devices).

5.2.1.2 STERRAD 100S

The devices were inoculated with spores of *B. stearothermophilus* suspended in 300 ppm hard water (AOAC preparation) supplemented with 5% fetal bovine serum. After drying, the devices were treated either by cleaning, then processing in the STERRAD® 100S sterilizer or by directly processing in the sterilizer, i.e., without cleaning.

The results show that the STERRAD® 100S process is not affected by the presence of an organic and inorganic challenge. The SLR for the unwashed, processed devices was 6.1 and for the washed, processed devices it was 6.2 (1 mm x 125 mm in length devices). The SLR for the unwashed, processed devices was 7.0 and for the washed, processed devices it was 6.9` (2 mm ID x 250 mm in length devices).

5.2.2 In-Use Sterility Testing

5.2.2.1 STERRAD 50

Devices representative of lumen claims for the STERRAD® 50 Sterilization System were selected for sterility testing. Devices tested were used in routine surgeries at local hospitals and included stainless steel lumen devices approximately 1 x 125mm and 2 x 250mm in length. The used devices were washed and dried

according to hospital protocol at the hospital site and transported to ASP to be sterilized in a STERRAD® 50 Sterilization System.

The results of the In-Use testing demonstrated that the STERRAD® 50 Sterilization System was shown to be an effective sterilizer of stainless steel lumen devices approximately 1 x 125mm and 2 x 250mm in length.

5.2.2.2 STERRAD 100S

Devices representative of lumen claims for the STERRAD® 100S Sterilization System were selected for sterility testing. Devices tested were used in routine surgeries at local hospitals and included stainless steel lumen devices approximately 1 x 125mm and 2 x 250mm. The used devices were washed and dried according to hospital protocol at the hospital site and transported to ASP to be sterilized in a STERRAD® 100S Sterilization System.

The results of the In-Use testing demonstrated that the STERRAD® 100S Sterilization System was shown to be an effective sterilizer of stainless steel lumen devices approximately 1 x 125mm and 2 x 250mm in length.

5.3 Toxicity Testing of Processed Materials

The cytotoxicity test results indicated that the titanium materials processed in the STERRAD® 50 & 100S Sterilizers did not induce *in vitro* cytotoxicity. The residues testing showed that the sterilization process leaves no toxic sterilant residuals on the materials processed.

6.0 OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies have demonstrated that medical devices with titanium surfaces and medical devices with only a single stainless steel lumen with:

- 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

may be processed in the STERRAD 50 & 100S Sterilization Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2003

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

Re: K023290
Trade/Device Name: Expanded Indications for the STERRAD® 50 and STERRAD® 100S Sterilizers
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF
Dated: February 4, 2003
Received: February 5, 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,

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

ADVANCED STERILIZATION PRODUCTS®
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REGULATORY AFFAIRS DEPARTMENT

510(k) Number (if known): K023290

Device Name: Expanded Indications for the STERRAD® 50 and STERRAD® 100S Sterilizers

Indications-For-Use:

This Premarket Notification is to expand the Indications for Use for the STERRAD 50 Sterilizer (K981625) and the STERRAD 100S Sterilizer (K991999) to include titanium as a compatible material and to expand the lumen sizes to include medical devices with only a single stainless steel lumen in the following configurations:

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

For information pertaining to previously cleared materials and lumen sizes, please reference K981625 and K991999.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Qian S. Lin

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

510(k) Number: K023290

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

(Optional Format 1-2-96)