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

JUN 1 5 2000

K991999

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

Kevin Corrigan
Manager of Regulatory Affairs
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Submission Date

June 11, 1999

Trade Name

STERRAD® 100S Sterilizer

Common Name

Hydrogen Peroxide Gas Plasma Sterilization System

Classification Name

Sterilizer, Class II

Legally Marketed Equivalent Device Name(s)

Hydrogen Peroxide Gas Plasma Sterilizer
STERRAD® 100 Sterilization System
STERRAD® 50 Sterilization System

Description of Device

The STERRAD® 100S 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 radio frequency (RF) electrical energy.

The equipment (hardware) for the STERRAD® 100S Sterilizer is the same as that of the predicate device, the STERRAD® 100 Sterilizer. (Note that the STERRAD® 100S Sterilizer does contain two additional hardware features, an oil return valve, added for customer convenience; and a door position sensor and control.) 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.

Statement of Intended Use

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

Metal and nonmetal lumened instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD® 100S Sterilizer.

Medical devices with only a single stainless steel lumen which has an inside diameter equal to or greater than 3 mm and a length less than or equal to 400 mm can be processed in the STERRAD® 100S Sterilizer.

Summary of Nonclinical Tests

Validation Testing

Testing was performed using the "overkill" approach.

Prevalidation Testing

- Test Organism: *B. stearothermophilus*
- Process Variables and Parameters: Rationale and Definition: A matrix experiment was performed that tested the process variables of chamber wall temperature and plasma power

within specification limits. The study showed that process lethality was unaffected over the range of process parameters tested.

- Characterization of the Pre-Exposure Plasma Phase: A series of experiments was performed to evaluate the effect of Pre-Exposure Plasma on the overall process lethality. The results of the studies showed that there is very little sporicidal activity in the Pre-Exposure Plasma phase alone or in combination with the Exposure 1 and Exposure 2 process phases.

STERRAD® 100S PROCESS VALIDATION

Demonstration of a Dose-Response Relationship to Increasing Hydrogen Peroxide Injection Volume

Dose-response testing was performed using various materials (representative of materials used in medical devices) as spore carriers.

B. stearothermophilus spore death kinetics data obtained for each material tested demonstrate a positive "dose response" to increasing volume of hydrogen peroxide injected under half-cycle conditions in the STERRAD® 100S Sterilization process. There were no spore survivors on any material with an injection volume of 720 µL or greater under half-cycle conditions. The nominal hydrogen peroxide injection volume for the half-cycle is 1440 µL. This result demonstrates that the dose response observation is not limited to a singular BI substrate or system and in each case >6 SLR were observed in a half-cycle exposure. These results validate a 10^{-6} SAL for a STERRAD® 100S Sterilizer full-cycle.

Surface Sterilization of Medical Device Materials

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

Inoculated spore carriers (with at least 1 x 10^6 *B. stearothermophilus* endospores) made from these materials were placed in the STERRAD® 100S Sterilizer validation load and then processed through the STERRAD® 100S Sterilizer at less than half-cycle conditions.

Results of these studies demonstrate an SAL of at least 10^{-6} for medical device surface sterilization in the complete STERRAD® 100S sterilization process for all materials listed as recommended for use in the STERRAD® 100S Sterilizer.

Mated Surfaces Sterilization

Half-cycle validation studies with mated biological indicator carriers were performed to demonstrate sterilization efficacy between mated surfaces of medical devices. Mated BIs with at least 1 x 10^6 *B. stearothermophilus* spores sandwiched in-between the mated metallic and polymer carriers were processed through the STERRAD® 100S Sterilization System at half-cycle conditions. An SAL of 10^{-6} was demonstrated for mated surface sterilization in the complete STERRAD® 100S Sterilization process.

Lumen Sterilization

Half-cycle and modified Total-kill Endpoint validation tests were performed using *B. stearothermophilus* endospores (>10^6 spores) inside stainless steel lumens (3 x 400 mm) placed within the STERRAD® 100S Sterilizer validation load of medical devices. There were no spore survivors after multiple half-cycles. These results demonstrate a SAL of 10^{-6} for the complete STERRAD® 100S Sterilization process.

ASP has conducted an additional test for nonmetallic lumens of 6 x 310 mm, similar to the testing that was performed for the predicate device. Stainless steel coupons inoculated with at least 10^6 spores of *B. stearothermophilus* were placed in the center of 6 x 310 mm polyethylene lumens as a test system for devices containing lumens with inner diameters of 6 mm or larger and lengths of 310 mm or shorter. The samples were processed with a validation load in the STERRAD® 100S Sterilizer under half-cycle conditions. Three cycles were performed with ten test samples in each cycle. All test samples were sterile. This result demonstrates an SAL of 10^{-6} for plastic lumens with inner diameters of 6 mm or larger and lengths of 310 mm or shorter processed in the STERRAD® 100S Sterilizer.

Tyvek-Mylar Pouched Device Sterilization

Half-cycle validation studies with 3 x 400 mm stainless steel straight lumens in Tyvek-Mylar pouches were performed to demonstrate sterilization efficacy with the STERRAD® 100S Sterilization System. The stainless steel lumens served to represent rigid stainless steel medical devices with lumens. Ten Tyvek pouched stainless steel lumens, with BIs (>10^6 *B. stearothermophilus* spores), were placed into a STERRAD® validation tray and processed through the STERRAD® 100S Sterilizer at half-cycle conditions. No spore survivors were observed with the half-cycle conditions.

Bacteriostasis Testing

A bacteriostasis study was performed with carriers of various materials. The materials were placed in open glass petri dishes and exposed to full cycle conditions in the STERRAD® 100S Sterilization system. Following exposure, the carriers were transferred to TSB and were then inoculated with less than 10 colony-forming units of *B. stearothermophilus* spores. All test carriers/materials demonstrated the desired outgrowth within the 14 day incubation period, however neoprene required the addition of catalase.

The test data indicate there is no bacteriostatic effect from the carriers processed through the STERRAD® 100S Sterilization System.

SUPPORTING MICROBIOLOGICAL TESTING

Sporicidal Microbiological Testing

AOAC Sporicidal Activity of Disinfectants tests using *B. subtilis* and *Cl. sporogenes* contaminated carriers (silk suture loops and penicylinders) were performed with the STERRAD® 100S Sterilization System. None of the carriers demonstrated growth.

Microbiological Spectrum of Activity

Using the predicate device, the STERRAD® 100 Sterilization System, it was shown that a hydrogen peroxide gas plasma process readily sterilizes the representative organisms.

Simulated Use Testing

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. Standard microbiological methods were used to determine the presence of surviving spores from each treatment.

The results show that the STERRAD® 100S process is minimally affected by the presence of an organic and inorganic challenge. Even if the user does not properly wash the devices, the sterilizer is still effective and inactivates highly resistant spores in a diffusion restricted environment such as the mated surfaces of scissors. When the devices are properly washed (i.e., processed in accordance with the labeling for the STERRAD® 100S Sterilizer) then a 6.1 log reduction is shown for the process.

In-Use Sterility Testing

Devices representative of surface-feature and lumen claims for the STERRAD® 100S Sterilization System were selected for sterility testing. Devices tested were used in routine surgeries at a local hospital and included stainless steel devices with open surfaces, mated or hinged surfaces and stainless steel lumened devices approximately 3 x 400 mm. 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.

Sterility testing was performed in accordance with the USP testing methods.

The results of the In-Use testing demonstrated that the STERRAD® 100S Sterilizer successfully sterilizes actual surgical instruments used in clinical cases.

The STERRAD® 100S Sterilization System was shown to be an effective sterilizer of general surgical stainless steel instruments/devices that have open surfaces, mated or hinged surfaces and stainless steel lumened devices approximately 3 x 400 mm.

In Use Bacteriostasis and Fungistasis Test

Devices representative of surface features and lumen claims for the STERRAD® 100S Sterilization System were selected for bacteriostasis and fungistasis testing. Devices tested include those with stainless steel open surfaces, stainless steel mated or hinged surfaces and stainless steel lumened devices approximately 3 x 400 mm.

USP sterility testing methods were used as testing guidelines. This study was performed to validate that processed instruments do not exhibit bacteriostatic or fungistatic effects on

microorganisms. After processing in the STERRAD® 100S Sterilization System, the devices (or swabs of the larger devices) were placed in TSB and FTM to which *Cl. sporogenes, C. albicans* or *B. subtilis* was added.

The results of this study demonstrate that there are no bacteriostatic or fungistatic effects seen with stainless steel open surfaces, stainless steel mated or hinged surfaces and stainless steel 3 x 400 mm lumened surgical instruments/devices when processed thorough the STERRAD® 100S Sterilization System.

Toxicity Testing of Processed Materials

Cytotoxicity and *in vivo* biocompatibility testing of materials processed in the STERRAD® 100S Sterilizer showed that the sterilization process leaves no toxic sterilant residuals on the materials processed.

Overall Performance Conclusions

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2000

Kevin Corrigan, R.A.C.
Director, Regulatory Affairs
Advanced Sterilization Products
Division of Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K991999
Trade Name: STERRAD® 100S Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: May 17, 2000
Received: May 18, 2000

Dear Mr. Corrigan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ADVANCED STERILIZATION PRODUCTS
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number: To Be Assigned

Device Name STERRAD® 100S Sterilizer

Indications For Use:

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

Metal and nonmetal lumened instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD® 100S Sterilizer. (See list of recommended Materials in Section 3 of the Operator's Manual)

Medical devices with only a single stainless steel lumen which has an inside diameter equal to or greater than 3 mm and a length less than or equal to 400 mm can be processed in the STERRAD® 100S Sterilizer.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991999