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ADVANCED STERILIZATION PRODUCTS
REGULATORY AFFAIRS DEPARTMENT

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person

Advanced Sterilization Products
A Division of Johnson & Johnson Medical, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person

Kevin Corrigan, RAC
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Submission Date

January 5, 1999

Trade Name

STERRAD® 50 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
Ethylene Oxide Gas Sterilizer
STERI-VAC Gas Sterilizer Model 5XL
3M Company
Chemolite Blvd. & Washington City Road 19
Cottage Grove, MN 55016

Description of Device

The STERRAD® 50 Sterilizer is a self-contained stand-alone system of hardware and software designed to sterilize certain medical instruments and devices, using a patented hydrogen peroxide gas plasma process. Sterilization is accomplished by injecting aqueous hydrogen peroxide into the vaporizer bowl where the solution is heated and transformed into a vapor, introducing this vapor into the process chamber under negative pressure and transforming the vapor into a gas plasma with RF electrical energy. The technology is particularly suited to the sterilization of heat and moisture sensitive instruments.

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, single-use biological and chemical indicators, printer paper and ink cartridges.

The sterilizer sits on a cart. The cart is designed for transportation of the sterilizer to its installation site, for mobility during servicing and as a structural support device.

Statement of Intended Use

The STERRAD® 50 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. (See list of recommended Materials in Section 3 of the Operator's Manual.)

The STERRAD® 50 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 (¼ inch) or larger and lengths of 310 mm (12 inches) or shorter can be processed in the STERRAD® 50 Sterilizer. (See list of recommended Materials in Section 3 of the Operator's Manual.)

Additionally, medical devices with only a single stainless steel lumen which has an inside diameter of 3 mm (1/8 inch) or larger and a length of 400 mm (15 ¾ inches) or shorter can be processed in the STERRAD® 50 Sterilizer.

Summary of Nonclinical Tests

1. Validation Testing

Testing was performed using the "overkill" approach

2. Prevalidation Testing

- Test Organism: *B. stearothermophilus*

- Process Parameter Rationale and Definition: A matrix experiment was performed that varied the process parameters of chamber wall temperature and plasma power within specification limits. The study showed the process parameters did not have an adverse effect on process lethality;

- 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.

3. STERRAD® 50 Process Validation

A. 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® 50 Sterilization process. There were no spore survivors on any material with an injection volume of 360 µL or greater under half-cycle conditions. The nominal hydrogen peroxide injection volume for the half-cycle is 1440 µL. There were no apparent differences in spore survival for any of the inoculated materials tested. The results obtained in this study demonstrate, at a minimum, a SAL of 10^{-6} for the complete STERRAD® 50 Sterilization process.

B. Surface Sterilization of Medical Device Materials

Surface sterilization efficacy studies were performed in the STERRAD® 50 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® 50 Sterilizer validation load and then processed through the STERRAD® 50 Sterilizer at less than half-cycle conditions using an injection volume of 720 µL of hydrogen peroxide. In addition, testing at less than half -cycle conditions with a reduced peroxide volume of 1080 µL (three-quarters

the minimum validation injection volume) was performed with material which exhibited fractional growth in the 720 µL cycles.

Results of these studies demonstrate an SAL of at least 10^{-6} for medical device surface sterilization in the complete STERRAD® 50 sterilization process.

C. 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® 50 Sterilization System at half-cycle conditions. No spore survivors were observed with the half-cycle. A SAL of 10^{-6} was demonstrated for mated surface sterilization in the complete STERRAD® 50 Sterilization process.

D. 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 mm x 400 mm) placed within the STERRAD® 50 Sterilizer validation load of medical devices. There were no spore survivors after the half-cycle. These results demonstrate a SAL of 10^{-6} for the complete STERRAD® 50 Sterilization process.

E. TYVEK-MYLAR POUCHED DEVICE STERILIZATION

Half-cycle validation studies with 3 mm x 400 mm stainless steel straight lumens in Tyvek-Mylar pouches were performed to demonstrate sterilization efficacy with the STERRAD® 50 Sterilization System. The stainless steel lumens served to represent rigid stainless steel medical devices with lumens. Ten Tyvek pouched stainless steel lumens, with BIs (≤ 1 x 10^{-6} *B. stearothermophilus* spores), were placed into a STERRAD® validation tray and processed through the STERRAD® 50 Sterilizer at half-cycle conditions. No spore survivors were observed with the half-cycle conditions

F. 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® 50 Sterilization system. Following exposure, the carriers were transferred to Trypticase Soy Broth and were then inoculated with less than 10 colony forming units (CFU) of *B. stearothermophilus* spores. All test carriers/materials demonstrated the desired outgrowth within the 14 day incubation period

The test data indicate there is no bacteriostatic effect from the carriers processed through the STERRAD® 50 Sterilization System.

4. Supporting Microbiological Testing

A. SPORICIDAL MICROBIOLOGICAL TESTING

AOAC Sporicidal Activity of Disinfectants tests using *B. subtilis* and *Clostridium sporogenes* contaminated carriers (silk suture loops and penicylinders) were performed with the STERRAD® 50 Sterilization System. None of the carriers demonstrated growth.

B. 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.

C. SIMULATED USE TESTING

Sterilant characterization pertains to the chemical entity, in our case, hydrogen peroxide. ASP previously submitted data on simulated use and hydrogen peroxide. It has not been included in this submission.

D. IN-USE STERILITY TESTING

Devices representative of surface-feature and lumen claims for the STERRAD® 50 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 mm 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® 50 Sterilization System.

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

The results of the In-Use testing demonstrated that the STERRAD® 50 Sterilizer successfully sterilizes actual surgical instruments used in clinical cases.

The STERRAD® 50 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 mm x 400 mm.

E. IN USE BACTERIOSTASIS AND FUNGISTASIS TEST

Devices representative of surface features and lumen claims for the STERRAD® 50 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 mm 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® 50 Sterilization System, the devices (or swabs of the larger devices) were placed in TSB and FTM to which *Cl. sporogenes, Candida 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 mm x 400 mm lumened surgical instruments/devices when processed thorough the STERRAD® 50 Sterilization System.

F. SIMULATED USE TESTING

The devices were inoculated with spores of *B. stearothermophilus* suspended in 5% fetal bovine serum in 95%, 300 ppm hard water (AOAC preparation). After the drying time, 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. Standard microbiological methods were used to determine the presence of surviving spores from each treatment.

The results show that the STERRAD® 50 process is minimally effected 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® 50 Sterilizer) then a 6.1 log reduction is shown for the process.

The data show that washing is a necessary part of the process as stated in the labeling.

5. Toxicity Testing of Processed Materials

Cytotoxicity and *in vivo* biocompatibility testing of materials processed in the STERRAD® 50 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® 50 Sterilizer is safe and effective for sterilization of medical devices within the indications for use for the sterilizer and establish equivalence of the STERRAD® 50 Sterilizer to the predicate device, the STERRAD® 100 Sterilizer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 1999

Kevin Corrigan, RAC
Manager of Regularoty Affairs
Advanced Sterilization Products®
33 Technology Drive
Irvine, California 92618

Re: K981625
Trade Name: STERRAD® 50 Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: December 10, 1998
Received: December 14, 1998

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number: K981625

Device Name STERRAD® 50 Sterilizer

Indications For Use:

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981625

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X

(Optional Format 1-2-96)