

JUN 15 1999



510(k) Summary - K991675

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, R.A.C.
 Manager of Regulatory Affairs
 Tel: (949) 453-6410
 Fax: (949) 789-3900

Submission Date

May 14, 1999

Trade Name

STERRAD® BI Test Pack

Common Name

Biological Indicator (Challenge Pack)

Classification Name

Class II

Legally Marketed Equivalent Device Name(s)

STERRAD® BI Test Pack, K921909, October 1, 1993.

DIVISION OF ETHICON, INC. • 33 TECHNOLOGY DRIVE • IRVINE, CA 92618 • (949) 581-5799 FAX (949) 789-3900

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

KCG 1675

Description of Device

The STERRAD® BI Test Pack (BI Test Pack) consists of a plastic tray with a clear top which contains a STERRAD® Biological Indicator paper strip containing 10^6 *Bacillus subtilis* var. *niger* spores, a STERRAD® BI Test Pack Indicator Strip and a length of latex tubing. The BI spore strip is packaged in a Tyvek/Mylar peel pouch to protect the spore strip during handling.

The narrow opening and channels leading to the interior of the BI Test Pack and the absorptive properties of the latex tubing provide a diffusion restrictive environment which contributes to the effective resistance of the indicator organism. Included with the BI Test Pack are individual BI spore strips in Tyvek/Mylar peel pouches to serve as positive controls in the microbiological testing.

The STERRAD® BI Test Pack Chemical Indicator Strip included in the Test Pack serves as a chemical process indicator (Class A per EN867-1) for the STERRAD® Sterilizer cycle. Exposure of the chemical indicator strip to the STERRAD® Sterilizer cycle results in a recognizable color change from red to yellow.

Statement of Intended Use

The STERRAD® BI Test Pack is intended to be used as a standard method for frequent monitoring of the STERRAD® 100 Sterilizer cycle*. It functions as a routine test pack with both a biological sterilization process indicator and a chemical process indicator.

Catalase Reagent is added to the Tryptic Soy Broth (TSB) medium, to neutralize the residual hydrogen peroxide on the biological indicator strip after sterilization.

* See precautionary statement in Instructions For Use concerning the use of this product with the STERRAD 50 Sterilizer which reads in part as follows:

PRECAUTION: The Certificate of Performance that accompanies these BI Test Packs contains data from the STERRAD® 100 Sterilizer. This information is unique to the STERRAD® 100 Sterilizer. The initial validation data submitted, based upon varying hydrogen peroxide concentration in the STERRAD® 50 Sterilizer, indicate that the BI Test Pack is acceptable for use with the STERRAD® 50 Sterilizer. The final performance data (D-value and Survival/Kill times) are not yet complete. Updated performance data for the BI Test Pack in the STERRAD® 50 Sterilizer will be provided by ASP as soon as it is available.

K991675

Description of Modification

The recommended incubation time for the STERRAD® BI Test Pack is being reduced to 48 hours based upon validation using *The Center for Devices and Radiological Health, FDA Guide for Validation of Biological Indicator Incubation Time* (1986).

For customer convenience, ASP now offers a catalase reagent for use with the STERRAD® BI Test Pack. Catalase has always been required for use with the STERRAD® BI Test pack. Previously, instructions were included for the user to make a catalase reagent. The reagent is supplied in single use dropper vials. The catalase reagent is sold in boxes of 50 vials.

Summary of Nonclinical Tests

Testing was conducted using the CDRH Guidance Document *Guide For Validation Of Biological Indicator Incubation Time* (1986). Partial sterilization cycles were based on decrease in diffusion and plasma time. Three different spore lots, from three different spore crops, were used for this validation. Each test was performed using a different lot of media. All valid tests showed at least 97% growth in 48 hours.

Catalase concentration was confirmed at end of shelf life by a stability study conducted at 4°C, 25°C and 40°C.

Aseptic fill of the catalase vials was confirmed by process validation.

Excess catalase was shown to not effect the growth of spores by a Bacteriostasis test.

Substantial Equivalence

The modified STERRAD® BI Test Packs have the following similarities to those which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principle,
- incorporate the same design
- incorporate the same materials
- have the same shelf life, and
- are packaged using the same materials and processes.

In summary, the STERRAD® BI Test Pack described in this submission is substantially equivalent to the predicate device



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

JUN 15 1999

Mr. Kevin Corrigan
Manager of Regulatory Affairs
Advanced Sterilization Products®
33 Technology Drive
Irvine, California 92618

Re: K991675
Trade Name: Modification of: STERRAD® BI Test Pack
Regulatory Class: II
Product Code: FRC
Dated: May 14, 1999
Received: May 17, 1999

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.

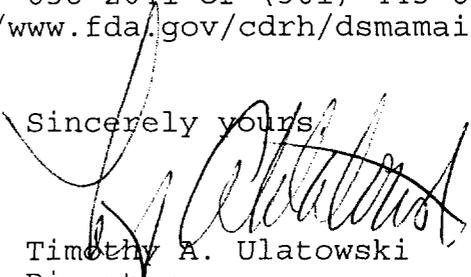
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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,



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

Enclosure



Indications for Use

510(k) Number: K991675 - Special 510(k) - Device Modification

Device Name STERRAD® BI Test Pack

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-the-Counter Use

(Optional Format 1-2-96)

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