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

K993775

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

Submission Date

November 5, 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 as modified in K991675, June 15, 1999.

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® Sterilizer cycles. It functions as a routine test pack with both a biological sterilization process indicator and a chemical process indicator.

Description of Modification

The modification to the STERRAD® BI Test Pack involves labeling only.

With the continued evolution of the STERRAD Sterilization System, new models of the sterilizer have been developed. The STERRAD BI Test Pack was originally cleared for use in the STERRAD 100 Sterilizer. In January of 1999, ASP received marketing clearance (K981625) for the STERRAD 50 Sterilizer and ASP currently has a 510(k) notification pending for another new sterilizer model, the STERRAD 100S Sterilizer. These two new sterilizers utilize a modification of the original STERRAD process. Consequently, new performance data (Survival and Kill characteristics) were needed for the STERRAD BI Test Pack in these new sterilizers.

This premarket notification modifies the Performance Certification of the STERRAD BI Test Pack to add the performance characteristics of the test pack in the STERRAD 50 and STERRAD 100S Sterilizers.

Summary of Nonclinical Tests

Testing was conducted to show that the Survival and Kill Performance Data generated for the STERRAD 50 and STERRAD 100S Sterilizers was accurate and reproducible using three different manufacturing lots of STERRAD BI Test Packs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2000

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

Re: K993775
Trade Name: STERRAD® BI Test Pack
Regulatory Class: II
Product Code: FRC
Dated: March 10, 2000
Received: March 13, 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 Susan Runner

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®
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REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number: To Be Assigned

Device Name STERRAD® BI Test Pack

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

(Optional Format 1-2-96)

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

Kim S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993775