510(k) Summary

MAY 12 2005

K 042450

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

Advanced Sterilization Products
Division of Ethicon, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person

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Or

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Summary Date

May 9, 2005

Common Name

Biological Indicator (Test Pack)

Classification Name

Class II

Officially Marketed Equivalent Device Name(s)

STERRAD® BI Test Pack
STERRAD® CycleSure® Biological Indicator

Description of Device

The STERRAD® NX Test Pack consists of several components, CycleSure® Self-Contained Biological Indicator (biological and chemical indicator), a vial into which the CycleSure is placed, a vial cap with orifice, and a pouch for holding the vial during the sterilization cycle.

Indications for Use

The STERRAD NX Test Pack is used for routine monitoring of the STERRAD® NX Sterilization cycle and is also used for the periodic testing of a STERRAD NX System using hospital-defined loads.

Summary of Non-clinical Tests

The STERRAD NX Test Pack has been evaluated for its resistance to both the Standard and Advanced sterilization cycles in the STERRAD NX Sterilizer.

A comparison of the Test Pack to the biological model developed for both the Standard and Advanced Cycles indicates that the Test Pack is at least as resistant to the sterilization process as the biological model. This is based on both survival curves and fraction negative data as a function of dose.

Test Packs containing three lots of CycleSure Biological Indictor were exposed to several doses of peroxide in both the Standard and Advanced Cycles. The survival curves for these were compared to the survival curves for the biological models developed for the

Standard and Advanced Cycles. With both cycles the Test Pack configuration was at least as resistant as the biological model.

Additionally, fraction negative data collected using Test Pack containing three lots of CycleSure BI when exposed to increasing volumes of peroxide in both the Standard and Advanced Cycles indicate that the Test Pack configuration is at least as resistant as the biological models.

Indicative functionality of the chemical indicator in the Test Pack configuration was evaluated using half cycle parameters of the Standard Cycle and the response was determined to be appropriate for a chemical indicator.

Overall Performance Conclusions

The STERRAD NX Test Pack has the necessary resistance relative to the biological model to be an appropriate challenge for testing both the Standard and Advanced Cycles of the STERRAD NX Sterilizer. The STERRAD NX Test Pack is substantially equivalent to the predicate devices STERRAD CycleSure Biological Indicator and STERRAD BI Test Pack

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2005

Advanced Sterilization Products
Dr. Joseph M. Ascenzi
Senior Manager, Regulatory Affairs
A Johnson & Johnson Company/Division of Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K042450
Trade/Device Name: STERRAD® NX Test Pack
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: April 1, 2005
Received: April 19, 2005

Dear Dr. Ascenzi:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Julia Y. Michaels, M.D.

Chiu Lin, Ph.D.
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®
a Johnson & Johnson company
Division of Ethicon, Inc.

Indications for Use Form

510(k) Number: K042450

Device Name: STERRAD® NX Test Pack

Indications for Use:

The STERRAD NX Test Pack is used for routine monitoring of the STERRAD® NX Sterilization cycle and is also used for the periodic testing of a STERRAD NX System using hospital-defined loads.

Prescription Use_____ (Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use__X__ (21 CFR 801Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOPTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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