510(k) Summary

K071537

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

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

Contact Person

Reuben Lawson
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Or

DEC 1 8 2007

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Summary Date

June 4, 2007

Common Name

Biological Indicator (Test Pack)

Classification Name

Class II

Officially Marketed Equivalent Device Name(s)

STERRAD® NX Test Pack
STERRAD® CycleSure® Biological Indicator

Description of Device

The STERRAD® 100NX 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 100NX Test Pack is used for routine monitoring of the STERRAD® 100NX Sterilization cycle and is also used for the periodic testing of a STERRAD 100NX System using hospital-defined loads.

Summary of Non-clinical Tests

The STERRAD 100NX Test Pack has been evaluated for its resistance to both the Standard and Flex Scope sterilization cycles in the STERRAD 100NX Sterilizer.

A comparison of the Test Pack to the biological model developed for both the Standard and Flex Scope 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 Flex Scope Cycles. The survival curves for these were compared to the survival curves for the biological models developed for the

Standard and Flex Scope 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 Flex Scope 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 100NX Test Pack has the necessary resistance relative to the biological model to be an appropriate challenge for testing both the Standard and Flex Scope Cycles of the STERRAD 100NX Sterilizer. The STERRAD 100NX Test Pack is substantially equivalent to the predicate devices, STERRAD NX Test Pack and STERRAD CycleSure Biological Indicator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Mr. Reuben Lawson
Regulatory Affairs Manager
Advanced Sterilization Products, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K071537
Trade/Device Name: STERRAD 100NX Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: November 30, 2007
Received: December 3, 2007

Dear Mr. Lawson:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K071537

Device Name: STERRAD 100NX Test Pack

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071537