K051643

510(k) Summary

AUG 19 2005

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

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

Contact Person

Joseph M. Ascenzi, PhD, RAC
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Summary Date

June 16, 2005

Common Name

Biological Indicator (Test Pack)

Classification Name

Class II

Officially Marketed Equivalent Device Name(s)

STERRAD® NX Test Pack (K042450)

Description of Device

The STERRAD® Sterilizer CycleSure® Test Pack consists of several components, CycleSure® Self-Contained Biological Indicator (biological and chemical indicator), a vial (with an orifice) into which the CycleSure is placed, a vial cap with orifice, and a pouch for holding the vial during the sterilization cycle. Two silicon mats are placed in the pouch during use to increase the resistance of the Test Pack, by acting as a reservoir for hydrogen peroxide.

Indications for Use:

The STERRAD® Sterilizer CycleSure® Test Pack is used for routine monitoring of the STERRAD 50, STERRAD 100S and STERRAD 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads.

Summary of Non-clinical Tests

The STERRAD Sterilizer Test Pack has been evaluated for its resistance in the STERRAD 50, STERRAD 100S, and STERRAD 200 Sterilizers.

A comparison of the Test Pack to the biological model developed for each of the STERRAD Sterilizers indicates that the Test Pack is more resistant to the sterilization process than the biological model.

Test Packs containing CycleSure Biological Indictor were exposed to increasing doses of hydrogen peroxide in each of the STERRAD Sterilization systems using half cycle parameters. The survival curves for the Test Pack were compared to the survival curves

for the biological models developed for each of the STERRAD Sterilization systems. It was demonstrated that with all three STERRAD Sterilization systems, the Test Pack configuration more resistant to the sterilization process than the biological model.

Indicative functionality of the chemical indicator in the Test Pack configuration was evaluated using half cycle parameters of the Standard Cycle and the data indicate that the chemical indicator responds appropriately when in the Test Pack configuration.

Overall Performance Conclusions

The STERRAD Sterilizer CycleSure Test Pack has the necessary resistance when compared to the biological model to be an appropriate challenge for testing of Sterilization processes in the STERRAD 50, STERRAD 100S, and STERRAD 200 Sterilizers. The STERRAD Sterilizer CycleSure Test Pack is substantially equivalent to the predicate devices, the STERRAD NX Test Pack.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2005

Dr. Joseph M. Ascenzi
Sr. Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Dr.
Irvine, California 92618

Re: K051643
Trade/Device Name: Sterrad Sterilizer Cyclesure Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: II
Product Code: FRC
Dated: August 2, 2005
Received: August 3, 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,

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: K051643

Device Name: STERRAD® Sterilizer CycleSure ® Test Pack

Indications for Use:

The STERRAD® Sterilizer CycleSure® Test Pack is used for routine monitoring of the STERRAD 50, STERRAD 100S and STERRAD 200 Sterilizers and is also used for the periodic testing of these sterilizers using hospital-defined loads.

Prescription Use _____ AND/OR Over-the-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda A. Murphy PhD 8/18/05

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

510(k) Number: K051643