510(k) Summary

K092755

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

Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

FEB 25 2011

Contact Person

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Summary Date

November 17, 2010

Common Name

Biological Indicator (Test Pack)

Classification Name

Class II

Officially Marketed Equivalent Device Name(s)

STERRAD® 100NX™ Test Pack
STERRAD® CycleSure® Biological Indicator

Description of Device

The STERRAD® 100NX™ EXPRESS Cycle Test Pack consists of the CycleSure® Self-Contained Biological Indicator (biological and chemical indicator), and a pouch for holding the vial during the sterilization cycle.

Indications for Use

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

Summary of Non-clinical Tests

The STERRAD® 100NX™ EXPRESS Cycle Test Pack has been evaluated for its resistance to the EXPRESS sterilization cycle in the STERRAD 100NX Sterilizer.

A comparison of the Test Pack to the biological model developed for the EXPRESS Cycle 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 EXPRESS Cycle. The survival curves for these were compared to the survival curves for the biological models developed for the EXPRESS Cycle. 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 the EXPRESS Cycle 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 EXPRESS Cycle and the response was determined to be appropriate for a chemical indicator.

Overall Performance Conclusions

The STERRAD® 100NX™ EXPRESS Test Pack has the necessary resistance relative to the biological model to be an appropriate challenge for testing the EXPRESS Cycle of the STERRAD 100NX Sterilizer. The STERRAD® 100NX™ EXPRESS Cycle Test Pack is substantially equivalent to the predicate devices, STERRAD® 100NX™ Test Pack and STERRAD® CycleSure® Biological Indicator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nancy Chu
Project Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

FEB 25 2011

Re: K092755
Trade/Device Name: STERRAD® 100NX EXPRESS Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. Chu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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
REGULATORY AFFAIRS DEPARTMENT

510(k) Number (if known): K092755

Device Name: STERRAD® 100NX EXPRESS Test Pack

Indications-For-Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** √
(PER 21 CFR 801.109)

Elizabeth F. Claunie-Wall (Optional Format 1-2-96)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092755