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

510(k) Summary

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

Advanced Sterilization Products
A Division of Johnson & Johnson Medical, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person

Kevin Corrigan, R.A.C.
Manager of Regulatory Affairs
Tel: (949) 453-6410
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Submission Date

April 17, 2003

Trade Name

STERRAD® CycleSure™ Biological Indicator

Common Name

Biological Indicator

Classification Name

Class II

Legally Marketed Equivalent Device Name(s)

STERRAD® CycleSure™ Biological Indicator, K994055, February 13, 2002.

Description of Device

The STERRAD® CycleSure™ Biological Indicator is a self-contained stand-alone biological monitor intended for the routine monitoring of the STERRAD® Sterilization Process. It consists of a glass fiber disc containing a minimum of 10^6 *Bacillus stearothermophilus* spores placed inside a plastic vial, a glass ampule containing nutrient growth medium also inside the vial, a cap and liner closing the vial and a chemical indicator on top of the cap. The cap contains two small circular openings that allow for diffusion of hydrogen peroxide vapor into the vial. The relatively small size of the circular openings serves as a restriction to this diffusion.

After exposure to the sterilization process, the cap is pressed down until firmly seated against the top of the vial in order to close the vial. The vial is then placed into the supplied tube crusher and squeezed until the media ampule is crushed. The entire device is then placed into an incubator and incubated in an upright position at 55° C to 60° C. After incubation, the medium in the vial is observed for a change in color from purple (indicating no growth) to yellow (indicating growth).

The STERRAD® CycleSure™ Chemical Indicator (on the cap) serves as a chemical process indicator (throughput indicator) [Class A per EN867-1] for the STERRAD® Sterilizer cycle. Exposure of the chemical indicator to the STERRAD® Sterilizer cycle results in a recognizable color change from red to yellow.

Statement of Intended Use

The STERRAD® CycleSure™ Biological Indicator is intended for use by healthcare providers for monitoring of the sterilization process in STERRAD® Sterilization Systems. STERRAD® CycleSure™ Biological indicator is designed to accompany medical devices placed in the sterilizer.

Description of Modification

The modification is to the methods used to test the product for final release. Additionally, the labeling for the device was modified to reflect this release testing based upon the BIER vessel.

Summary of Nonclinical Tests

18 different lots of CycleSure BIs were tested using the new methods. Based upon the results obtained, the methods used were consistent and appropriate for the evaluation and release of CycleSure BIs.

Substantial Equivalence

The modified STERRAD CycleSure Biological Indicators have the following similarities to those which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principle,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged using the same materials and processes.

In summary, the STERRAD CycleSure Biological Indicator described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2003

Mr. Kevin Corrigan
Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

Re: K031226
Trade/Device Name: STERRAD® CycleSure™ Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: April 17, 2003
Received: April 21, 2003

Dear Mr. Corrigan:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim 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®
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REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number:

Device Name STERRAD® CycleSure™ Biological Indicator

Indications For Use:

The STERRAD® CycleSure™ Biological Indicator is intended to be used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycles.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

(Optional Format 1-2-96)

Qian S. Lin

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

510(k) Number K031226