510(K) Summary

STERRAD® CycleSure®Biological Indicator

MAY 2 4 2007

1. Sponsor:

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

Contact Person:

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Summary Date: March 27, 2007

2. Device Name

a. Proprietary Name: STERRAD® CycleSure® Biological Indicator
b. Device Common/Usual Name: Biological indicator
c. Device Classification Name: Biological Sterilization Process Indicators

3. Identification of Predicate Device:

STERRAD® CycleSure®Biological Indicator, K031226, May 2, 2003 and
STERRAD® CycleSure® Biological Indicator, K994055, February 13, 2002

4. Device Description:

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 $1x10^6$ *Geobacillus stearothermophilus* spores, a glass ampoule containing nutrient growth medium, 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.

The STERRAD® CycleSure® Biological Indicator is identical in design (with exception of fill volume) and performance specifications (with exception of incubation time) to the predicate device.

5. Indication For Use:

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

The Indication For Use is identical for the predicate device and proposed device.

6. Description of Modification

The culture media has been modified to achieve 24 hours incubation time (read out time) and the labeling for the device was modified to reflect the reduce incubation time of 24 hours. Additionally, growth media fill volume has been modified.

7. Performance Test Data

The studies were conducted to confirm the performance and quality characteristics of the modified culture media to evaluate suitability of the media for use in the STERRAD® CycleSure® Biological Indicator.

The growth media was tested for the color reversion after the growth and it was determined that color did not revert and yellow (positive) color was stable for up to seven days of incubation time. This test result confirms performance characteristic of the growth media.

The Bacteriostatis test was conducted to evaluate growth promotion and bactriostatic effect of pH indicator. Test data demonstrated that growth media was not bacteriostatic and met the specifications of performance characteristics.

The Fill Volume Determination study was conducted to determine if the growth media maintains enough volume to support positive growth and test data met the specifications.

The study was performed to determine the culture media reformulation can meet the reduced incubation time of 24 hours and test data confirms the 24 hours incubation time.

The design verification was done to confirm that the culture media consistently support growth of the *Geobacillus stearothermophilus* organism. Test data also confirms the growth support of the indicator organism.

The accelerated stability study was performed to evaluate the initial shelf life of the culture media to use in the STERRAD® CycleSure® Biological Indicator. The test result supports eighteen months of shelf life.

The performance and quality testing results of the media formulation has shown to promote growth, no color reversion, was not bacteriostatic and meet the 24 hours incubation time.

8. Substantial Equivalence

The modified STERRAD® CycleSure® Biological Indicator have the following similarities to the predicate device:

- have the same indicated use
- use same operating principles
- incorporate same design (with exception of culture media formulation and fill volume)
- have the same shelf life
- have same performance characteristics (with exception of incubation time)
- are packaged using the same materials and process

In addition, the test result indicates that proposed STERRAD® CycleSure® Biological Indicator is substantially equivalent to currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Mr. Yogi Shah
Project Manager, Regulatory Affairs
Advanced Sterilization Products, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K071014
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: May 8, 2007
Received: May 9, 2007

Dear Mr. Shah:

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.

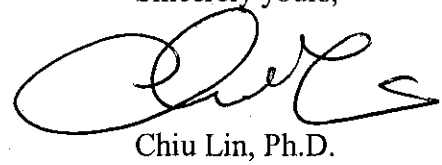
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,
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Office of Device Evaluation
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Radiological Health

Enclosure

cc: HFZ-401 DMC

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REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number: To be assigned K 071014

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.

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) Page 1 of 1

Sign-Off)
ion of Anesthesiology, General Hospital,
ction Control, Dental Devices

510(k) Number: K 071014

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