K994055

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

FEB 1 3 2002

510(k) Summary

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

Advanced Sterilization Products
Division of Ethicon, Inc.
33 Technology Drive
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Contact Person

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Submission Date

February 6, 2002

Trade Name

STERRAD® CycleSure™ Biological Indicator

Common Name

Biological Indicator

Classification Name

Class II

Legally Marketed Equivalent Device Name(s)

3M™ Attest™ Biological Indicator
STERRAD® BI Test Pack

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 seal 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 to be used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycles.

Summary of Nonclinical Tests

Chemical Indicator Validation

Effects of a simulated heavy load, no load, presence of plasma, and absence of hydrogen peroxide on the performance of the chemical indicator component of the STERRAD® CycleSure™ Biological Indicator were evaluated by observing the color of the chemical indicators before and after processing in the STERRAD® Sterilization System.

The results of these performance studies indicate that the chemical indicator component of the STERRAD® CycleSure™ Biological Indicator successfully changes color from red to yellow when processed in the STERRAD® 100 Sterilization System under maximum and minimum exposure to hydrogen peroxide.

Additionally, the chemical indicator did not change color when water was substituted for hydrogen peroxide in the injection phase of the cycle. This demonstrates that the color change of the chemical indicator is due to the chemical reaction between the dye and hydrogen peroxide molecules during the diffusion phase and not due to the plasma phase of the STERRAD® 100 Sterilization Process.

Chemical Indicator Stability Validation

Color stability of the chemical indicator component of the STERRAD® CycleSure™ Biological Indicator was evaluated before and after processing in the STERRAD® Sterilization System. The results of stability studies indicate that the unprocessed chemical indicators maintain their red color for at least 24 months when stored at the storage temperatures specified in the product labeling (15°C to 25°C).

Post-processing color stability of the chemical indicator was also evaluated after processing in the STERRAD® Sterilization System. Stability results, based upon real time aging, demonstrate that the indicator color is stable for at least 7 months after processing in a STERRAD® Sterilizer.

In addition to the stability studies, functionality studies were conducted to evaluate the ability of the chemical indicator, following aging at 30°C/75% R.H., to change color when processed in the STERRAD® Sterilization Systems. Chemical indicators from three different lots, aged up to 24 months, successfully changed color from red to yellow upon processing.

Population and Performance Characteristics Determination

The spore population and performance characteristics of the STERRAD® CycleSure™ Biological Indicators were determined using a Biological Indicator Evaluation Resistometer (BIER Vessel) following the in accordance with ISO 11138-1.

Incubation Time Determination

Testing was conducted using CDRH Guidance Document *Guide For Validation Of Biological Indicator Incubation Time* (1986). Three different lots of STERRAD® CycleSure™ Biological Indicator (each using a different spore crop and media lot), each consisting of one hundred samples, were tested to determine the required incubation time. The sterilization cycle parameters were reduced in order to obtain 30-80% surviving samples for each lot tested. Processed STERRAD® CycleSure™ Biological Indicators were incubated for 7 days at 55-60^0 C. Samples were observed and the results were recorded on a daily basis. Based on the results from this testing, the minimum incubation time required for the STERRAD® CycleSure™ Biological Indicator was determined to be 48 hours.

Bacteriostasis

Bacteriostasis testing was performed in the STERRAD® 100 Sterilizer to represent the minimum hydrogen peroxide exposure conditions (6 mg/L injected) and in the STERRAD® 50 Sterilizer to represent the maximum hydrogen peroxide exposure conditions (two injections at 14.3 mg/L injected).

STERRAD® 100 Sterilizer

Twenty STERRAD® CycleSure™ Biological Indicator samples were prepared with uninoculated glass fiber discs. Ten samples were processed in the STERRAD®100 Sterilization System as test samples and ten were unprocessed as negative controls. Ten additional STERRAD® CycleSure™ Biological Indicator samples were prepared without the glass fiber discs for positive controls, this sample set also remained unprocessed. All samples were inoculated with $\leq$10 *Bacillus stearothermophilus* spores/10µL. Growth of the test organism was observed in all samples when incubated at 55°-60°C. No bacteriostatic effects due to the materials of the STERRAD® CycleSure™ Biological Indicator and the STERRAD® 100 Sterilization process were observed.

STERRAD® 50 Sterilizer

Twenty STERRAD® CycleSure™ Biological Indicator samples were prepared with uninoculated glass fiber discs. Ten samples were processed in the STERRAD®50 Sterilization System as test samples and ten were unprocessed as negative controls. Ten additional STERRAD® CycleSure™ Biological Indicator samples were prepared without the glass fiber discs for positive controls, this sample set also remained unprocessed. All samples were inoculated with $\leq$10 *Bacillus stearothermophilus* spores/10µL. Growth of the test organism was observed in all samples when incubated at 55° - 60°C. No bacteriostatic effects due to the materials of the STERRAD® CycleSure™ Biological Indicator and the STERRAD® 50 Sterilization process were observed.

Growth Media Validation

The growth media was tested for color reversion after growth and it was determined that the yellow color was stable for up to 7 days of total incubation.

Studies were conducted to confirm the performance and quality characteristics of the growth medium and to evaluate the suitability of the media for use in the STERRAD® CycleSure™ Biological Indicator. The performance characteristics of the media to be evaluated include: growth promotion and bacteriostasis of the pH indicator. The quality characteristics of the media to be evaluated include: pH, color, appearance, and stability.

Media lots were prepared and aged at room temperature (20-25° C). ASP currently has data for 12 months real-time aging and the testing is ongoing.

The aged media was shown to promote growth, was not bacteriostatic and the evaluated quality characteristics met specification.

Additional studies, conducted on media ampuls stored at at 55° C accelerated aging conditions, were conducted to determine the performance and quality characteristics of the growth media and to evaluate the end of shelf-life suitability of the media for use in the STERRAD® CycleSure™ Biological Indicator. The performance characteristics of the media to be evaluated include: growth promotion and bacteriostasis of the pH indicator. The quality characteristics of the media to be evaluated include: pH, color, appearance, and stability. Media lots were prepared and aged at elevated temperature (55° C). ASP has data for 36 months shelf-life based on these accelerated aging studies.

The accelerated aged media was shown to promote growth, was not bacteriostatic and the evaluated quality characteristics met specification.

Performance Validation

The STERRAD® CycleSure™ Biological Indicator samples made with three different spore crops were used to evaluate the effect of varying concentrations of hydrogen peroxide on the STERRAD® CycleSure™ Biological Indicator performance at half cycle conditions in the STERRAD®100, 100S, and 50 Sterilizers.

The results indicated that the inactivation of the STERRAD® CycleSure™ Biological Indicator was consistently obtained after processing through a half cycle with a reduced injection volume of 59% nominal hydrogen peroxide in each of the STERRAD® Sterilizers. All the chemical indicators from STERRAD® CycleSure™ Biological Indicator changed color from red to yellow, indicating exposure to hydrogen peroxide.

STERRAD® CycleSure™ Biological Indicator Shelf-Life (Stability) Validation

An ongoing product stability testing program is currently underway. Three different manufacturing lots of STERRAD® CycleSure™ Biological Indicators (each made with a different spore crop, a different growth media lot and a different chemical indicator lot) were used. A portion of each lot was placed into the following storage conditions:

- 1 group from each lot at 2°C (+/- 2° C) refrigerated.
- 1 group from each lot at 25°C/50%RH (+/-3° C & +/-5%RH)

Samples from each storage condition are periodically removed from storage and tested for spore population, D-value (fraction negative method), and chemical indicator functionality. Testing will continue up to 24 months.

ASP currently has completed testing for up to 4 months. All lots have shown to be within specifications for the labeled storage conditions (2° C – 25° C) when tested through 18 months of storage. These data demonstrate that the STERRAD® CycleSure™ Biological Indicator is stable for a shelf-life of up to 18 months. ASP will continue to collect data as part of ongoing stability studies and may extend the labeled shelf-life of the product based upon the same acceptance criteria used here.

Overall Performance Conclusions

The nonclinical studies demonstrate that the STERRAD® CycleSure™ Biological Indicator is safe and effective for the routine monitoring of the STERRAD® Sterilization Systems and establish equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

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

Re: K994055
Trade/Device Name: STERRAD® CycleSure™ Biological Indicator
Regulation Number: 880.2800
Regulation Name: Biological Indicator
Regulatory Class: II
Product Code: FRC
Dated: December 20, 2001
Received: December 21, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital 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: K994055

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)

Division Sign-Off
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994055