



Food and Drug Administration
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October 29, 2015

Advanced Sterilization Products
Ms. Sun Choi
Regulatory Affairs Specialist IV
33 Technology Dr.
Irvine, CA 92618

Re: K151971

Trade/Device Name: STERRAD[®] CYCLESURE[®] 24 Biological Indicator

Regulation Number: 21 CFR 880.2800

Regulation Name: Biological Sterilization Process Indicator

Regulatory Class: II

Product Code: FRC

Dated: October 13, 2015

Received: October 14, 2015

Dear Ms. Choi:

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 contact 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>. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151971

Device Name

STERRAD® CYCLESURE® 24 Biological Indicator

Indications for Use (Describe)

The STERRAD CYCLESURE 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of the following STERRAD Sterilization Systems and has been validated for use in health care facilities:

- STERRAD 100S
- STERRAD 50
- STERRAD 200
- STERRAD NX®
- STERRAD 100NX® (Standard, Flex and Express Cycles)
 - o For STERRAD 100NX DUO Cycle in the United States, the STERRAD CYCLESURE 24 Biological Indicator should only be used in a test pack configuration (REF 20243).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Contact Person: Sun Choi
Regulatory Affairs Specialist IV
Telephone: (949) 453-6378
Fax: (949) 798-3900

Date Prepared: July 13, 2015

II. DEVICE

Name of Device: STERRAD[®] CYCLESURE[®] 24 Biological Indicator
Common or Usual Name: Biological Indicator
Classification Name: Biological Sterilization Process Indicator (21 CFR 880.2800)
Regulatory Class: II
Product Code: FRC

III. PREDICATE DEVICE

STERRAD CYCLESURE 24 Biological Indicator K123017

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The STERRAD CYCLESURE 24 Biological Indicator (BI) 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 1×10^6 *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.

V. INDICATIONS FOR USE

The STERRAD CYCLESURE 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of the following STERRAD Sterilization Systems and has been validated for use in health care facilities:

- STERRAD 100S
- STERRAD 50
- STERRAD 200
- STERRAD NX®
- STERRAD 100NX® (Standard, Flex and Express Cycles)
 - For STERRAD 100NX DUO Cycle in the United States, the STERRAD CYCLESURE 24 Biological Indicator should only be used in a test pack configuration (REF 20243).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed modification is to extend the labeled shelf life of the STERRAD CYCLESURE 24 BI. The intended use/indications for use, technological characteristics, design, materials, and principles of operation have not changed. Refer to Table 1 for comparison between modified and predicate devices for the STERRAD CYCLESURE 24 BI.

Table 1: Comparison between Modified and Predicate Devices

	Predicate Device: STERRAD CYCLESURE 24 BI (K123017)	Modified Device: STERRAD CYCLESURE 24 BI
Intended Use / Indications for Use	The STERRAD CYCLESURE 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of the following STERRAD Sterilization Systems: <ul style="list-style-type: none"> • STERRAD 100S • STERRAD 50 • STERRAD 200 • STERRAD NX • STERRAD 100NX (Standard, Flex and Express Cycles) <ul style="list-style-type: none"> ○ For STERRAD 100NX DUO Cycle in the United States, the STERRAD CYCLESURE 24 Biological Indicator should only be used in a test pack configuration (REF 20243). 	Same as predicate

	Predicate Device: STERRAD CYCLESURE 24 BI (K123017)	Modified Device: STERRAD CYCLESURE 24 BI
Technological Characteristics	The STERRAD CYCLESURE 24 BI 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 1×10^6 <i>Geobacillus stearothermophilus</i> 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.	Same as predicate
Organism	<i>Geobacillus stearothermophilus</i> ATCC 7953	Same as predicate
Viable Spore Population	Minimum of 1×10^6 spores/BI	Same as predicate
Carrier Material	Glass Fiber	Same as predicate
Resistance Characteristics	D-value at 2.5 mg/L of hydrogen peroxide: $\geq \sim 1$ second Survival Time: calculated based on D-value Kill Time: 60 seconds	Same as predicate
Incubation Temperature	55 - 60°C	Same as predicate
Incubation Time	24 hours to 3 days (72 hours)	Same as predicate
Chemical Indicator	A throughput indicator, changes color from red to golden yellow or bronze to indicate exposure to hydrogen peroxide	Same as predicate
Shelf-life	6 months	9 months

VII. PERFORMANCE DATA

The modified and predicate devices have the same intended use/indications for use, technological characteristics, design, materials, and principles of operation. The proposed modification is to extend the labeled shelf life of the STERRAD CYCLESURE 24 BI from 6 months to 9 months. Stability studies were conducted to demonstrate that the specifications (D-value, survival time, kill time, spore population, and positive BI color test) are maintained throughout the proposed labeled shelf life of the modified device. Refer to Table 2 for the summary of stability studies.

Table 2: Summary of Performance Testing

Study Type	Description	Results
Stability	Verification of spore population for 9 month labeled product shelf life	Passed
	Verification of resistance characteristics (D-value, survival time, and kill time) for 9 month labeled product shelf life	Passed

VIII. CONCLUSIONS

Stability study results demonstrate that the specifications (D-value, survival time, kill time, spore population, and positive BI color test) are maintained throughout the proposed labeled shelf life (9 months) of the STERRAD CYCLESURE 24 BI. Modified and predicate devices have the same intended use/indications for use, technological characteristics, design, materials, and principles of operation.

Therefore, Advanced Sterilization Products considers the modified device with the extended shelf life to be substantially equivalent to its predicate device.