December 27, 2018

Advanced Sterilization Products (ASP)
Ms. Sun Choi
Principal Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92618

Re: K182404
Trade/Device Name: STERRAD VELOCITY Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 29, 2018
Received: December 31, 2018

Dear Sun 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182404

Device Name

STERRAD VELOCITY™ Biological Indicator

Indications for Use *(Describe)*

The STERRAD VELOCITY™ Biological Indicator, in conjunction with the STERRAD VELOCITY Reader, is intended to be used as a standard method for frequent monitoring and periodic testing of the following STERRAD Sterilization Systems:

- STERRAD® 100NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear™ Technology
- STERRAD NX® (STANDARD and ADVANCED Cycles) with and without ALLClear™ Technology
- STERRAD® 100S

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.**

This section applies onlyto requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

## Advanced Sterilization Products
## STERRAD VELOCITY™ Biological Indicator

General Information

| | |
|---|---|
| Submitter Name: | Advanced Sterilization Products<br>Division of Ethicon, Inc., a Johnson & Johnson company |
| Address: | 33 Technology Drive<br>Irvine, CA 92618 |
| Contact Person: | Sun Choi<br>Principal Regulatory Affairs Specialist<br>Phone: 949-453-6378<br>Email: sjchoi@its.jnj.com |
| Date Prepared: | December 20, 2018 |
| 510(k) Number: | K182404 |

**Device Name**

| | |
|---|---|
| Proprietary Name: | STERRAD VELOCITY™ Biological Indicator |
| Common Name: | Biological Indicator |
| Classification Name: | Biological Sterilization Process Indicator |
| Device Class: | Class II |
| Product Code: | FRC |
| CFR Section: | 21 CFR 880.2800 |

**Predicate Device**

- Primary Predicate Device: STERRAD VELOCITY™ Biological Indicator, K170039 cleared June 20, 2017

  Note: The subject device is identical to the predicate STERRAD VELOCITY Biological Indicator (K170039). Only the indications for use have been modified to incorporate the periodic testing indication.

- Reference Device: STERRAD® 100NX DUO Cycle Test Pack, K111391 cleared September 26, 2012

**Device Description**

The STERRAD VELOCITY Biological Indicator is a self-contained biological indicator, used in conjunction with the STERRAD VELOCITY Reader, that is intended for frequent monitoring and periodic testing of the STERRD Sterilization Cycles, using rapid readout technology that provides a final fluorescence result in 30 minutes at the incubation temperature of 57 ± 2ºC.

The STERRAD VELOCITY BI can also be determined as growth-positive or growth-negative via an optional visual pH-based color change result (using bromocresol purple) if used for frequent monitoring purposes. When using this method, the biological indicator must be cultured in an incubator at 55-60°C for 5 to 7 days to get a final visual result.

The STERRAD VELOCITY BI consists of a glass fiber disc containing a minimum of $1 \times 10^6$ *Geobacillus stearothermophilus* (ATCC 7953) spores and a glass ampoule containing nutrient growth medium and non-fluorescent substrate, as well as a vial, cap, cap label, insert, and chemical indicator. The spore disc, growth media ampoule, and insert are contained in a clear plastic vial with a vented cap. The cap is designed with sterilant ingress openings which allow for penetration of hydrogen peroxide vapor into the vial during the sterilization process. The chemical indicator (CI), placed on the top of the cap, is a Type 1 process indicator that changes color from red/pink to yellow or yellow with some red/orange/brown dots when exposed to hydrogen peroxide.

The STERRAD VELOCITY BI has the same α-glucosidase enzyme system for the fundamental scientific technology as the predicate device cleared under K170039. The α-glucosidase enzyme, which is generated naturally during growth of *G. stearothermophilus* and released during spore germination, hydrolyzes the bond between the glucose and 4-methylumbelliferyl (4-MU) moieties of 4-methylumbelliferyl α-D-glucopyranoside (α-MUG). In the combined state, α-MUG is not fluorescent. Once the bond between the glucose and 4-MU is hydrolyzed, the 4-MU component becomes fluorescent when excited with UV light. Therefore, the α-glucosidase enzyme in its active state can be detected by measuring the fluorescence produced by the enzymatic hydrolysis of α-MUG.

The resultant fluorescent by-product (4-MU), is detected by the Reader and the fluorescent signal is used to determine the positive or negative result of the biological indicator. The measured enzyme activity is reduced upon exposure to hydrogen peroxide. As the enzyme activity is directly correlated with the spore outgrowth, the reduction of the enzyme activity below a certain level indicates that all spores have been inactivated. The level of the fluorescence response is determined using the algorithm developed for the STERRAD VELOCITY BI and is used to distinguish between the positive and negative responses.

## Intended Use/Indications for Use

The STERRAD VELOCITY Biological Indicator, in conjunction with the STERRAD VELOCITY Reader, is intended to be used as a standard method for frequent monitoring and periodic testing of the following STERRAD Sterilization Systems:

- STERRAD® 100NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear™ Technology
- STERRAD NX® (STANDARD and ADVANCED Cycles) with and without ALLClear Technology
- STERRAD 100S

The Indications for Use statement for the STERRAD VELOCITY Biological Indicator has been expanded to incorporate the periodic testing indication. The subject and its predicate device share the same intended use for monitoring of hydrogen peroxide gas plasma sterilization processes.

## Comparison of Technological Characteristics with Predicate Device/Reference Device

The subject device and predicate device have the same technological characteristics based on their use in the monitoring of hydrogen peroxide gas plasma sterilization processes. Refer to the following

table for a comparison of the subject device and predicate device/reference device characteristics, showing the similarities and differences.

**Substantial Equivalence Comparison Table**

| Device Characteristics | Reference Device | Predicate Device | Subject device |
|---|---|---|---|
| | **STERRAD 100NX DUO Cycle Test Pack (K111391)** | **STERRAD VELOCITY BI (K170039)** | **STERRAD VELOCITY BI with Expanded Indications (K182404)** |
| Intended Use | Routine monitoring of the sterilizer cycle (hydrogen peroxide gas plasma) | Monitoring of hydrogen peroxide gas plasma sterilization processes | Same |
| Indications for Use | The STERRAD 100NX DUO Cycle Test Pack is used for routine monitoring of the STERRAD 100NX DUO Sterilization Cycle and is also used for the periodic testing of a STERRAD 100NX System DUO Cycle, using hospital-defined loads containing devices that do not exceed claims of the cycle. The STERRAD 100NX DUO Cycle Test Pack consists of a STERRAD® CYCLESURE® 24 Biological Indicator, vial and cap to hold the BI. | Used as a standard method for frequent monitoring of the following STERRAD Sterilization Systems:<br>• STERRAD 100NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear Technology<br>• STERRAD NX (STANDARD and ADVANCED Cycles) with and without ALLClear Technology<br>• STERRAD 100S | Used as a standard method for frequent monitoring and periodic testing of the following STERRAD Sterilization Systems:<br>• STERRAD 100NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear Technology<br>• STERRAD NX (STANDARD and ADVANCED Cycles) with and without ALLClear Technology<br>• STERRAD 100S |
| Organism (Spore, Species, Strain) | *Geobacillus stearothermophilus* ATCC 7953 | *Geobacillus stearothermophilus* ATCC 7953 | Same |
| Viable Spore Population | $\geq 1x10^6$ CFU/BI | $\geq 1x10^6$ CFU/BI | Same |
| Carrier Material | Glass Fiber | Glass Fiber | Same |
| Device Design | Self-contained biological indicator in test pack configuration | Self-contained biological indicator | Same as predicate device |
| Resistance Characteristics | Equal to or greater than the most difficult item routinely processed (biological model). | Tested at 5 mg/L hydrogen peroxide:<br>D-value $_{5mg/L}$: $\geq$ 1 second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1. | • Tested at 5 mg/L hydrogen peroxide:<br>D-value $_{5mg/L}$: $\geq$ 1 second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1.<br>• Equal to or greater than the most difficult item routinely processed (biological model). |

| Device Characteristics | Reference Device | Predicate Device | Subject device |
|---|---|---|---|
| | **STERRAD 100NX DUO Cycle Test Pack (K111391)** | **STERRAD VELOCITY BI (K170039)** | **STERRAD VELOCITY BI with Expanded Indications (K182404)** |
| Rapid Readout Technology | N/A | The α-glucosidase enzyme system is generated naturally during growth of *Geobacillus stearothermophilus*. The α-glucosidase enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected in the reader. The fluorescence signal is used to determine a positive or negative result. | Same as predicate device |
| Incubation Temperature | 55 - 60ºC | 57 +/- 2ºC | Same as predicate device |
| Reduced Incubation Time | 24-hour visual pH color change results | 30-minute fluorescence results read in STERRAD VELOCITY Reader and optional visual pH color change results at 5 to 7 days. | Same as predicate device |
| Holding Time | Immediately after sterilization cycle | Within 2 hours after sterilization cycle | Same as predicate device |
| Carrier growth inhibition/media growth promotion | No bacteriostatic effects that inhibit the growth of the indicator microorganism | No bacteriostatic effects that inhibit the growth of the indicator microorganism | Same |
| Chemical Indicator | Throughput indicator, changes color from red to golden yellow or bronze to indicate exposure to hydrogen peroxide | Type 1 process indicator changes color from red/pink to yellow or yellow with some red/orange/brown dots to indicate exposure to hydrogen peroxide. | Same as predicate device |
| Shelf Life | 12 months | 9 months | Same as predicate device |

The subject device and its predicate device (STERRAD VELOCITY BI) have the same intended use and indications for use with one modification to the subject device, which is to incorporate the periodic testing indication. Further, the subject device and predicate device share the same technological characteristics.

## Non-Clinical Data

Performance testing was conducted to satisfy the requirements for the STERRAD VELOCITY BI with periodic testing indication that is the subject of this 510(k), as outlined in the Guidance for Industry and FDA Staff: *Biological Indicator (BI) Premarket Notification [510(k)] Submissions, Section 10, Test Pack,* issued on October 4, 2007.

The subject device was evaluated for its challenge to all claimed STERRAD Cycles and the resistance of the subject device was compared to the biological models for all claimed STERRAD Cycles.

The study results indicated that the resistance of the subject device was greater than the biological model for all claimed STERRAD Cycles, and all fluorescence-negative results were obtained in triplicate runs. The results demonstrated that the STERRAD VELOCITY BI is qualified for its design and performance for periodic testing indication in all claimed STERRAD Cycles.

All testing yielded passing results. This testing is summarized in the following table.

**Summary of Performance Testing**

| Performance Testing | Description | Pass / Fail |
|---|---|---|
| Performance Study in STERRAD 100NX | Design Evaluation and Performance Qualification for Periodic Testing in STERRAD 100NX STANDARD and FLEX Cycles with and without ALLClear Technology | Pass |
| | Design Evaluation and Performance Qualification for Periodic Testing in STERRAD 100NX EXPRESS Cycle with and without ALLClear Technology | Pass |
| | Design Evaluation and Performance Qualification for Periodic Testing in STERRAD 100NX DUO Cycle | Pass |
| Performance Study in STERRAD NX | Design Evaluation and Performance Qualification for Periodic Testing in STERRAD NX STANDARD and ADVANCED Cycles with and without ALLClear Technology | Pass |
| Performance Study in STERRAD 100S | Design Evaluation and Performance Qualification for Periodic Testing in STERRAD 100S Cycle | Pass |

## Clinical Data

No clinical data was generated in support of this Premarket Notification.

## Summary

The subject device and its reference device (STERRAD 100NX DUO Cycle Test Pack) have the same periodic testing indication; however, there are differences in their device designs. The subject device is a self-contained biological indicator, whereas the reference device is a self-contained biological indicator in a test pack configuration. Non-clinical data demonstrates that the use of a test pack configuration is not necessary for the subject device.

## Conclusion

The subject device (STERRAD VELOCITY Biological Indicator) is substantially equivalent to the claimed predicate and reference devices.