January 23, 2020

Advanced Sterilization Products (ASP)
Elsie Kim
Sr. Regulatory Affairs Program Lead
33 Technology Drive
Irvine, California 92618

Re: K192025
Trade/Device Name: STERRAD VELOCITY Biological Indicator/Process Challenge Device and Reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: December 20, 2019
Received: December 23, 2019

Dear Elsie Kim:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Sreekanth Gutala, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K192025

Device Name
STERRAD VELOCITY® Biological Indicator/Process Challenge Device and Reader

Indications for Use *(Describe)*
STERRAD VELOCITY® Biological Indicator/Process Challenge Device, 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.

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K192025 510(k) Summary

Advanced Sterilization Products, Inc.

STERRAD VELOCITY® Biological Indicator/Process Challenge Device and Reader

This summary of 510(k) information is being submitted per 21 CFR 807.92.

General Information

Submitter Name:	Advanced Sterilization Products
Address	33 Technology Drive, Irvine, CA 92618
Contact Person:	Elsie Kim Sr. Regulatory Affairs Program Lead Phone: 949-932-4234 Email: elsie.kim@asp.com

Date Prepared:	January 22, 2020

Device Name

Proprietary Name:	STERRAD VELOCITY® Biological Indicator/Process Challenge Device and Reader
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

Predicate Device: STERRAD VELOCITY Biological Indicator, K182404 cleared December 27, 2018

Description

STERRAD VELOCITY Biological Indicator/Process Challenge Device

The STERRAD VELOCITY Biological Indicator (BI) /Process Challenge Device (PCD) 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 STERRAD Sterilization Cycles, using rapid readout technology that provides a final fluorescence result in 15 minutes at the incubation temperature of 57 ± 2ºC.

The STERRAD VELOCITY BI/PCD 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/PCD consists of a glass fiber disc containing a minimum of 1 x 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/PCD has the same α-glucosidase enzyme system for the fundamental scientific technology as the predicate device cleared under K182404. 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/PCD and is used to distinguish between the positive and negative responses.

STERRAD VELOCITY READER

The STERRAD VELOCITY Reader is designed to automatically read the STERRAD VELOCITY BI/PCD to obtain the final fluorescence result in 15 minutes at the incubation temperature of 57 ± 2°C. The STERRAD VELOCITY Reader utilizes the fluorometric enzymatic assay method to detect the enzyme activity from the BI and the fluorescence emitted from the BI is converted into a voltage. This voltage reading is then used by the fluorescence algorithm in the Reader to determine the final fluorescence result.

There are eight individual BI incubation wells in the STERRAD VELOCITY Reader. Its heater system is designed to maintain the biological indicators at 57 ± 2°C to promote the outgrowth of the indicator organisms. Each well contains an ultraviolet light source that excites fluorescence in the growth medium, and a photodetector to detect that fluorescence.

The STERRAD VELOCITY Reader features a touch screen for an effective user interface. Directly under each well is a well number illuminated by a well status indicator light. Three colors (white, green, and red) and two states (off and solid line) are used for the indicator light on the touch screen to show the status of the BI processing. The Reader has a thermoplastic exterior which makes it easy to clean and maintain. A built-in barcode scanner coupled with network connectivity makes maintaining sterilization records easy.

The STERRAD VELOCITY Reader of the subject device has the same hardware and uses same fundamental scientific technology as the predicate device cleared under K182404. Only the algorithm for

fluorescence reading has been modified in the subject device to reduce the fluorescence readout time from 30 minutes to 15 minutes.

Intended Use/Indications for Use

The STERRAD VELOCITY® Biological Indicator/Process Challenge Device, 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 intended use of the modified device, as described in the labeling, has not changed as a result of the modification which is the subject of this submission.

The name of the device is changed from STERRAD VELOCITY Biological Indicator to STERRAD VELOCITY Biological Indicator/Process Challenge Device (or BI/PCD) as the periodic testing indication was cleared for the predicate device under K182404.

Comparison of Technological Characteristics with Predicate Device

The modified 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 modified device and predicate device characteristics, showing the similarities and differences.

Technological Characteristic Comparison Table

Device Characteristics	Predicate Device	Subject Device
	STERRAD VELOCITY BI (K182404) and Reader	**STERRAD VELOCITY BI/PCD and Reader with 15-minute fluorescence readout**
Intended Use	Monitoring of hydrogen peroxide gas plasma sterilization processes	Same
Indications for Use	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	Same
Organism (Spore, Species, Strain)	*Geobacillus stearothermophilus* ATCC 7953	Same

Device Characteristics	Predicate Device	Subject Device
	STERRAD VELOCITY BI (K182404) and Reader	**STERRAD VELOCITY BI/PCD and Reader with 15-minute fluorescence readout**
Viable Spore Population	$\geq 1x10^6$ CFU/BI	Same
Carrier Material	Glass Fiber	Same
Device Design	Self-contained biological indicator	Same
Resistance Characteristics	• Tested at 5 mg/L hydrogen peroxide: D-value $_{5mg/L}$: ≥ 1 second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1. • Equal to or greater than the most difficult item routinely processed (biological model).	Same
Rapid Readout Technology	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
Incubation Temperature	57 +/- 2ºC	Same
Reduced Incubation Time	30-minute fluorescence results read in STERRAD VELOCITY Reader and optional visual pH color change results at 5 to 7 days.	**15-minute** fluorescence results read in STERRAD VELOCITY Reader and optional visual pH color change results at 5 to 7 days.
Holding Time	Within 2 hours after sterilization cycle	Same
Carrier growth inhibition/media growth promotion	No bacteriostatic effects that inhibit the growth of the indicator microorganism	Same
Chemical Indicator	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
Shelf Life	9 months	Same
Method of Fluorescence Detection	UV LED, optical filters, with sensing by photodiode	Same
Indicator of Adequate Sterilization Cycle	"Negative" displayed on LCD Display	Same
Indicators of Possible Sterilization Cycle Failure	"Positive" displayed on LCD Display, Audible Alarm	Same
Incubation Wells	8 incubation/reader wells	Same

Device Characteristics	Predicate Device	Subject Device
	STERRAD VELOCITY BI (K182404) and Reader	**STERRAD VELOCITY BI/PCD and Reader with 15-minute fluorescence readout**
Voltage Range	100-240 Volts AC (12 Volt DC conversion for internal circuitry)	Same
Product Safety	UL/IEC 61010-1	Same
EMC Compliance	FCC Part 15, Subpart B, Class A	Same

The modified device and its predicate device have the same intended use and indications for use.

The sole difference between the predicate and modified device relates to the decreased time to read, associated with an update to the Reader to include a 15-minute fluorescence readout algorithm. The modified and predicate devices have identical technological characteristics.

Summary of Non-Clinical Testing

Verification testing was conducted in support of the modification to the STERRAD VELOCITY BI/PCD and Reader that is the subject of this submission; all testing yielded passing results. This testing is summarized in the following table.

Summary of Non-Clinical Testing

Performance Testing	Description	Acceptance Criteria	Pass/Fail
Hydrogen Peroxide Dose Response and Sterilization Verification	The fluorescence results collected for previously submitted dose response testing were reanalyzed using the modified algorithm. No additional sterilization cycles were performed.	General trend of increasing number of sterile BIs (growth and fluorescence) with increasing hydrogen peroxide injection volume. All BIs negative for fluorescence and growth at full cycle.	Pass
Design evaluation and Performance Qualification for Periodic Testing	The fluorescence results collected for the previously submitted dose response testing were reanalyzed using the modified algorithm and compared with the biological model data. No additional sterilization cycles were performed.	Fluorescence results demonstrate equal or greater resistance to the biological model by comparison of BI complete inactivation points. The BI shall demonstrate all fluorescence-negative results in full cycle	Pass
Verification of Reduced Incubation Time	The fluorescence data collected for the previously submitted reduced incubation time verification study were reanalyzed using the modified algorithm and compared to the 7-day incubation spore growth results from the same study. No additional sterilization cycles were performed.	BI fluorescence-positive for greater than 97.0% of all growth-positive BIs.	Pass

Performance Testing	Description	Acceptance Criteria	Pass/Fail
Verification of BI Holding Time	The fluorescence data collected for the previously submitted holding time verification study were reanalyzed using the modified algorithm. No additional sterilization cycles were performed.	The number of fluorescence-positive BIs after 2 hours of holding time is not less than the number of fluorescence-positive BIs read immediately after exposure to H_2O_2.	Pass
System Level Error Check	This study verified that the STERRAD VELOCITY Reader with the modified software algorithm meets the system level error check performance requirements as defined in the product design specification and system requirements for the STERRAD VELOCITY Reader.	The reader shall accurately interrogate the BI or provide an error message to alert the user when the BI is subject to rotational movement or handling.	Pass
Operational Vibration	This study verified that the STERRAD VELOCITY Reader with the proposed algorithm continues to meet the requirements for operational vibration as defined in the product design specification and system requirements for the STERRAD VELOCITY Reader.	The reader shall accurately interrogate the BI when subjected to random vibration per C-S 1-9711-002 in the 3 orthogonal axes for the entire incubation cycle.	Pass
Software Verification and Validation	STERRAD VELOCITY Reader Software Verification and Validation, including Cybersecurity Testing	The modified software meets specifications and functions correctly for the product's intended use.	Pass

Clinical Data

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

Conclusions

The conclusions drawn from the performance tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device STERRAD VELOCITY Biological Indicator (K182404).