January 3, 2019

STERIS Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K183294
Trade/Device Name: CELERITY 20 HP Biological Indicator, CELERITY HP Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 26, 2018
Received: November 27, 2018

Dear Anthony Piotrkowski:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183294

Device Name

Celerity 20 HP Biological Indicator

Indications for Use *(Describe)*

The Celerity 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 and s2 Low Temperature Sterilization Systems.
- STERRAD® 100S Sterilizer (Default Cycle)
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear
- Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear

When used in conjunction with the Celerity HP Incubator, the Celerity 20 HP BI provides a fluorescent result within 20 minutes

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

☐ Prescription Use (Part 21CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*

K183294

Device Name
CELERITY 20 HP Challenge Pack

Indications for Use *(Describe)*

The CELERITY 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For
CELERITY 20 HP Biological Indicator
And
CELERITY 20 HP Challenge Pack

Sponsor Facility

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Manufacturing Facility

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Director Regulatory Affairs

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Submission Date: January 2, 2019

Premarket Notification Number: K183294

1. Device Name

Trade Name:	CELERITY 20 HP Biological Indicator
Common/usual Name:	Biological Indicator (BI, SCBI)
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

2. Predicate Device Biological Indicator

CELERITY 20 HP Biological Indicator, K172752 (modified under K181429)

3. Description of Device – Biological Indicator

The product is intended to monitor the vapor phased hydrogen peroxide sterilization cycles described in the indications for use. It produces an optical change (signal) that is detected by the STERIS proprietary reader, CELERITY 20 HP Incubator, within 20 minutes to confirm the viability of the biological indicator at the end of a sterilization process. The product consists of *Geobacillus stearothermophilus* spores and a defined nutrient media in a plastic vial. A reporter enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.

4. Intended Use/ Indications for Use – Biological Indicator

The Celerity 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 and s2 Low Temperature Sterilization Systems.
- STERRAD® 100S Sterilizer (Default Cycle)
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear
- Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear

When used in conjunction with the Celerity HP Incubator, the Celerity 20 HP BI provides a fluorescent result within 20 minutes.

5. Technical Characteristics Comparison Table – Biological Indicator

Table 5-1. BI Physical Description and Technological Properties vs the Predicate Device

Feature	CELERITY 20 HP BI K183294 (proposed)	CELERITY 20 HP BI Predicate (K172752)	Comparison
Intended Use	The Celerity 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 and s2 Low Temperature Sterilization Systems. • STERRAD® 100S Sterilizer (Default Cycle) • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear When used in conjunction with the Celerity HP Incubator, the Celerity 20 HP BI provides a fluorescent result within 20 minutes.	The CELERITY Biological Indicator is used for routine monitoring, and qualification of the Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Low Temperature Sterilizers in healthcare facilities. When used in conjunction with the VERIFY CELERITY 20 HP Incubator, the CELERITY 20 HP Biological Indicator provides a fluorescent result within 20 minutes.	The Fast Cycle is a new cycle in the V-PRO s2 Low Temperature Sterilizer, which has been submitted in a separate premarket notification. Testing to support claims in sterilizers with ALLClear is included in this submission. Indications for STERRAD sterilizers were cleared under K172474.
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same
Mechanism of action	An enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.	An enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.	Same
Accessories	CELERITY HP Incubator* (K171587)	CELERITY HP Incubator* (K171587)	Same
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	1.0 – 4.0 x 10^6 spore/BI	Same
Resistance characteristics	Resistance @ 9.1 mg/L H_2O_2: • D-value $\geq$ 6 sec • Survival Time $\geq$ 4 sec • Kill Time $\leq$ 7 min	Resistance @ 9.1 mg/L H_2O_2: • D-value > 3 sec • Survival Time $\geq$ 4 sec • Kill Time $\leq$ 6 min	Increased minimum D-value specification, within the range of the predicate device.

Feature	CELERITY 20 HP BI K183294 (proposed)	CELERITY 20 HP BI Predicate (K172752)	Comparison
Culture Conditions	55- 59°C, media included in BI, 20-minute incubation time.	55- 59°C, media included in BI, 20-minute incubation time.	Same
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, cap with recovery media.	Same
Process indicator	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	Same
Shelf-life	Currently 10 months Target of 13 months	Currently 10 months Target of 13 months	Real-time testing ongoing

6. Summary of Nonclinical Performance Tests – Biological Indicator

Performance testing demonstrated that the subject device met its acceptance criteria and the results are summarized in **Table 5-2** below.

Table 5-2. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
BI Simulated Use in the V-PRO maX 2 Sterilizer Fast Non Lumen Cycle	All BIs processed in full cycles will be negative for growth	PASS
Recoverable Population after exposure to STERRAD ALLClear	Recoverable Population of 50 – 300% of the label claim	PASS

7. Device Name – Challenge Pack

Trade Name: CELERITY 20 HP Challenge Pack

Common/usual Name: Biological Indicator Challenge Pack

Device Classification: Class II

Classification Name: Sterilization Process Indicator
(21 CFR 880.2800, FRC)

8. Predicate Device – Challenge Pack

CELERITY 20 HP Challenge Pack K173488
(NOTE: The proposed and predicate devices are identical)

9. Description of Device – Challenge Pack

The CELERITY 20 HP Challenge Pack (pack), is used by healthcare providers for qualification testing of the V-PRO Low Temperature Sterilization Systems. The pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The user places the pack into the V-PRO Sterilizer and performs a sterilization cycle. After cycle completion, the VERIFY HPU Chemical Indicator (CI) and the CELERITY 20 HP Biological Indicator (BI) contained in the pack are retrieved. The CI is assessed for a passing color change immediately and the BI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The BI is activated by sealing the vial and thus puncturing the cap to release the contained media.

The activated SCBI is incubated at 55-60 °C in the CELERITY HP Incubator* for a final determination of viability within 20 minutes of incubation.

10. Intended Use/ Indications for Use – Challenge Pack

The CELERITY 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.

11. Technical Characteristics Comparison Table – Challenge Pack

Table 5-3. Summary of Pack Physical Description and Technological Properties

Feature	CELERITY pack K183294 (Proposed)	CELERITY pack (K173488) Predicate	Comparison
Intended Use / Indication for Use	The CELERITY 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	The CELERITY 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	Same
General Design	Sealed sterilization pouch containing SCBI, CI and barrier material.	Sealed sterilization pouch containing SCBI, CI and barrier material.	Same
Biological Indicator	Celerity 20 HP Biological Indicator	Celerity 20 HP Biological Indicator	Same
Chemical Indicator	VERIFY HPU Chemical Indicator	VERIFY HPU Chemical Indicator	Same
Means to distinguish processed pack from unprocessed	Proposed device's internal indicator is visible through the pack.	Proposed device's internal indicator is visible through the pack.	Same
Required accessories	CELERITY HP Incubator* (K171587)	CELERITY HP Incubator* (K171587)	Same

12. Summary of Nonclinical Performance Tests – Challenge Pack

Performance testing demonstrated that the subject device met its acceptance criteria and the results are summarized in **Table 5-4** below.

Table 5-4. Summary of Non-Clinical Testing

Test	Acceptance Criteria	Conclusion
Simulated Use	Demonstrate the pack shows passing results in worst-case load under worst-case sterilization conditions	PASS
Cycle-Specific Testing	The pack provides an equivalent or greater challenge to the claimed cycle than the biological model under worst-case conditions.	PASS

13. Conclusion

Based on the intended use, technological characteristics and the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, the CELERITY 20 HP Biological Indicator (cleared in K172752) Class II (21 CFR 880.2800, product code FRC).

The CELERITY 20 HP Challenge Pack has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as the legally marketed predicate device, K173488, Class II (21 CFR 880.2800, Product code FRC).

** The Celerity HP Incubator was cleared in K171587 under the name "VERIFY Incubator for Assert VH2O2 SCBI"*