June 15, 2023

STERIS Corporation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K223717
Trade/Device Name: Celerity 5 HP Biological Indicator; Celerity 5 HP Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: May 19, 2023
Received: May 19, 2023

Dear Gregory Land:

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,

Christopher K. Dugard -S

Clarence W. Murray, III, PhD
Deputy 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223717

Device Name

Celerity 5 HP Biological Indicator;
Celerity 5 HP Challenge Pack

Indications for Use *(Describe)*

Celerity 5 HP Biological Indicator
The Celerity 5 HP Biological Indicator (BI) is used 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, maX 2, 60 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, Express and DUO Cycles of the STERRAD® 100NX® Sterilizer with or without ALLClear®.
When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.

Celerity 5 HP Challenge Pack
The Celerity 5 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 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) ☒ 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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary
For
Celerity 5 HP Biological Indicator
And
Celerity 5 HP Challenge Pack

Sponsor Facility
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax: (440)357-9198

Manufacturing Facility

STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax: (440) 392-7896

Contact
Gregory Land
Lead Regulatory Affairs Specialist
Phone: (440) 392-7424
Email: greg_land@steris.com

Submission Date: June 13, 2023

K Number: __K223717_____

1 Device Name

Celerity 5 HP Biological Indicator

Trade Name:	Celerity 5 HP Biological Indicator
Common/usual Name:	Biological Indicator
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

Celerity 5 HP Challenge Pack

Trade Name:	Celerity 5 HP Challenge Pack
Common/usual Name:	Biological Indicator
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

2 Predicate Device

Celerity 5 HP Biological Indicator

Proprietary Name	Celerity 20 HP Biological Indicator
Common/usual Name	Biological indicator
Classification Name:	Indicator, Biological Sterilization Process
510(k) Submitter/Holder	STERIS Corporation
510(k) Number:	K183294

Celerity 5 HP Challenge Pack

Proprietary Name	Celerity 20 HP Biological Indicator
Common/usual Name	Biological indicator
Classification Name:	Indicator, Biological Sterilization Process
510(k) Submitter/Holder	STERIS Corporation
510(k) Number:	K183294

3 Description of Device

Celerity 5 HP 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, STERIS Celerity Incubator, within 5 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.

Celerity 5 HP Challenge Pack

The CELERITY 5 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 5 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 2 hours prior to activation.

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

The activated BI is incubated at 55-60 °C in the CELERITY Incubator for a final determination of viability within 5 minutes of incubation.

4 Intended Use/Indications for Use

Celerity 5 HP Biological Indicator

The Celerity 5 HP Biological Indicator (BI) is used 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, maX 2, 60 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, Express and DUO Cycles of the STERRAD® 100NX® Sterilizer with or without ALLClear®.

When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.

Celerity 5 HP Challenge Pack

The Celerity 5 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 V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the Sterilizers.

5 Summary of Technical Characteristics

Table 1. Biological Indicator Subject Device Comparison to the Predicate Device

Feature	CELRITY 5 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (K183294)	Comparison
Intended Use	The Celerity 5 HP Biological Indicator (BI) is used for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast and	The Celerity 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles:	Proposed device has a 5-minute read time

Feature	CELRITY 5 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (K183294)	Comparison
	Flexible Cycles of the V-PRO 1, 1 Plus, maX, maX 2, 60 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, Express and DUO Cycles of the STERRAD® 100NX® Sterilizer with or without ALLClear®. When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.	• Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO® 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.	
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	Automated incubator / reader	Automated incubator / reader	Same
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	1.0 – 4.0 x 10^6 spore/BI	Same
Resistance	Resistance @ 9.1 mg/L H_2O_2: • D-value ≥ 6 sec • Survival Time ≥ 4 sec • Kill Time ≤ 7 min	Resistance @ 9.1 mg/L H_2O_2: • D-value ≥ 6 sec • Survival Time ≥ 4 sec • Kill Time ≤ 7 min	Same
Culture Conditions	55- 59°C, media included in BI, 5-minute incubation time.	55- 59°C, media included in BI, 20-minute incubation time.	Similar

Feature	CELRITY 5 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (K183294)	Comparison
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	8 months	10 months	Similar

Table 2: Challenge Pack Comparison to Predicate Device

Feature	CELERITY 5 HP Challenge pack Proposed	CELERITY 20 HP Challenge pack (K173488) Predicate	Comparison
Intended Use / Indication for Use	The CELERITY 5 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 5 HP Biological Indicator	Celerity 20 HP Biological Indicator	Similar

Feature	CELERITY 5 HP Challenge pack Proposed	CELERITY 20 HP Challenge pack (K173488) Predicate	Comparison
Chemical Indicator	Celerity HP Chemical Indicator	VERIFY HPU Chemical Indicator	Same – brand name has changed
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 Incubator (K223715)	CELERITY HP Incubator* (K171587) Celerity Incubator (K213881)	Similar

6 Summary of nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in Table 3 below.

Table 3. Summary of Non-clinical Testing

Test	Description	Acceptance Criteria	Conclusion
Viable Spore Population	Study to demonstrate that the product meets its specification for the spore population.	Average population for each lot of 1.0 x 106 - 4.0 x 106 CFU/BI	Pass
Resistance Characteristics Study	Study to verify that the Celerity 5 Biological Indicator meets the acceptance criteria for resistance. Acceptance criteria are designed to demonstrate comparable or greater resistance values than the predicate device	• D-Value: 2-20 seconds • All Survive: ≤ 4 seconds • All Kill: ≥ 6 minutes	Pass
Carrier and Pack Material Growth Inhibition Evaluation	Study to demonstrate that the primary packaging material used in the manufacture of the Biological Indicator (BI) does not hinder, or otherwise affect, the outgrowth of a low number of Geobacillus stearothermophilus spores	All BIs inoculated with *Geobacillus stearothermophilus* spores demonstrate growth	Pass
Holding Time Assessment	Study to demonstrate the labeled hold time of the BI	120 minutes	Pass
Signal Generation	Study to demonstrate the PBS media	All BIs will demonstrate a positive fluorescent signal	Pass

	contained in the cap of the Celerity 5 HP Biological Indicator is able to generate a detectable fluorescent signal from viable *G. stearothermophilus* organisms.		
Simulated Use Testing – V-PRO	Study to demonstrate that the Project Blayze Biological Indicator (BI) for Gaseous Hydrogen Peroxide Sterilization Processes functions appropriately when processed in the claimed sterilizer cycles with a validated load.	All BIs processed in a full cycle will demonstrate a negative signal corresponding to a no-growth result upon seven day incubation.	Pass
Simulated Use Testing – STERRAD	Study to demonstrate the Project Blayze Biological Indicator (BI) for Gaseous Hydrogen Peroxide Sterilization Processes functions appropriately when processed in STERRAD® Sterilizers with a validated load.	All BIs processed in a full cycle will demonstrate a negative signal corresponding to a no-growth result upon seven day incubation.	Pass
Population after ALLClear Exposure	Study to demonstrate ALLClear preconditioning does not impact BI performance.	Each Bi signal evaluation was positive following exposure to the All-Clear precondition treatment The mean population of each BI exposed to the All-Clear precondition treatment was within 50-300% of the unexposed control mean population.	Pass
Reduced Incubation Time - User mode	Study to verify Reduced Incubation Time of the BI	Study will demonstrate that 97% or greater of the positive	Pass

		samples at seven days also gave a positive signal at the claimed RIT time	
Reduced Incubation Time – Engineering Mode	Study to verify the Reduced Incubation Time of 5-minute correlates to a 20-minute result like the predicate device and 7 day growth.	study will demonstrate that 97% or greater of the positive samples at seven days also gave a positive signal at the claimed RIT time	Pass
Celerity 5 HP Challenge Pack			
Simulated Use Testing	Study to demonstrate performance of challenge pack under worst-case conditions.	Demonstrate the pack shows passing results in worst-case load under worst-case sterilization conditions	Pass
Dose Response Testing	Study to demonstrate the challenge pack provides adequate challenge to perform intended use.	The pack provides an equivalent or greater challenge to the claimed cycle than the biological model under worst-case conditions.	Pass

7 Conclusion

Based on the intended use, technological characteristics and the nonclinical tests performed, the subject Celerity 5 HP Biological Indicator device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, the CELERITY 20 HP Biological Indicator, K183294 Class II [21 CFR 880.2800(a)], product code FRC.

Based on the intended use, technological characteristics and the nonclinical tests performed, the subject Celerity 5 HP Challenge Pack device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, the CELERITY 20 HP Challenge Pack, K183294 Class II [21 CFR 880.2800(a)], product code FRC.