March 18, 2022

Steris
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K220473
Trade/Device Name: CELERITY 20 HP Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: February 17, 2022
Received: February 18, 2022

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/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,

Clarence W. Murray, III, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220473

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) ☒ 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."

K220473 510(k) Summary
For
CELERITY 20 HP Challenge Pack

Sponsor Facility

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Manufacturing Facility

STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax No: (440) 392-7896

Contact: Anthony Piotrkowski
Director, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 357-9189
e-mail: tony_piotrkowski@steris.com

Submission Date: February 17, 2022

1. Device Name

Trade Name:	CELERITY 20 HP Challenge Pack
Common/usual Name:	Biological Indicator Challenge Pack
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

2. Predicate Device

CELERITY 20 HP Challenge Pack K173488
Note: K183294 is the most recent clearance for the CELERITY 20 HP Challenge pack but this submission specifically addresses the original clearance under K173488.

3. Description of Device

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.

4. Intended Use/ Indications 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.

5. Summary of Technological Characteristics

A comparison of technical characteristics are summarized in **Table 5-1**.

Table 5-1 Summary of pack Physical Description and Technological Properties

Feature	CELERITY pack (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	CELERITY HP Incubator	Same

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-2** below.

Table 5-2. 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 (Fast Non Lumen Cycle of V-PRO maX 2 Sterilizer)	**PASS** All CI complete change All BI inactivated

7. Conclusion

The conclusion drawn from the non-clinical performance test demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device, K173488, Class II (21 CFR 880.2800, Product code FRC).