February 9, 2018

Steris Corporation
Jennifer Nalepka
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K172752
Trade/Device Name: CELERITY 20 HP Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: September 11,2017
Received: January 10, 2018

Dear Jennifer Nalepka:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael J. Ryan -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)*

K172752

Device Name
CELERITY 20 HP Biological Indicator

Indications for Use *(Describe)*

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.

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

D 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.

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510(k) Summary
For K172752
CELERITY 20 HP Biological Indicator

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Submission Date: September 11, 2017

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, FRC)

2. Predicate Device

CELERITY 20 HP Biological Indicator, K171504 (previously named "VERIFY Assert VH2O2 Self-Contained Biological Indicator")—Note: The BI is identical to that provided in K171504 only the indications for use have been changed.

3. Description of Device

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

The CELERITY 20 HP 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 CELERITY 20 HP Incubator, the CELERITY 20 HP Biological Indicator provides a fluorescent result within 20 minutes.

5. Summary of Technical Characteristics

A comparison of technical characteristics versus the predicate is summarized in **Table 5-1.**

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

Feature	CELERITY 20 HP BI (proposed)	CELERITY 20 HP BI Predicate (K171504)	Comparison
Intended Use	The CELERITY 20 HP 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 Sterilizer in healthcare facilities. When used in conjunction with the CELERITY Incubator, the CELERITY 20 HP Biological Indicator provides a fluorescent result within 20 minutes.	The CELERITY 20 HP Biological Indicator is used for routine monitoring, and qualification of the Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX and 60 Low Temperature Sterilizer in healthcare facilities. When used in conjunction with the CELERITY Incubator, the CELERITY 20 HP Biological Indicator provides a fluorescent result within 20 minutes.	The proposed and predicate devices are identical. The Fast Non Lumen Cycle is a new cycle in the V-PRO maX 2 Low Temperature Sterilizer, which has been submitted in a separate premarket notification. The proposed indications for use include information about the incubator/reader and read time that are supported through testing in accordance with FDA guidance for BI 510(k).
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	Both contain greater than 10^6 spores/BI.
Resistance characteristics	Resistance @ 9.1 mg/L H_2O_2: • D-value > 3 sec • Survival Time ≥ 4 sec • Kill Time ≤ 6 min	Resistance @ 9.1 mg/L H_2O_2: • D-value > 3 sec • Survival Time ≥ 4 sec • Kill Time ≤ 6 min	Same
Culture Conditions	55- 59°C, media included in BI, 20-minute incubation time.	55- 59°C, media included in BI, 20-minute incubation time.	RIT Testing and ISO 11138-1 media testing verifies performance
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 3 months Target of 15 months	Currently 3 months Target of 15 months	Real-time testing ongoing

***Note:* The BI is identical to that provided in K171504 only the indications for use have been changed.**

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
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

Performance testing of the predicate in V-PRO Sterilizers has been previously submitted in K171504. A summary of the testing can be found in **Table 5-3.**

Table 5-3. Summary of Non-clinical Testing Previously Submitted in K171504.

Test	Acceptance Criteria	Conclusion
Reduced Incubation Time (RIT) Testing	Meets FDA's requirement of > 97% alignment of the 20-minute results with the conventional incubation time of 7 days	PASS
Viable spore population	$1.0 – 4.0 \times 10^6$ spore/SCBI	PASS
Resistance	D-value > 3 sec	PASS
Survival Time	Survival Time ≥ 4 sec	PASS
Kill Time	Kill Time ≤ 6 min	PASS
Carrier growth inhibition / media growth promotion	Positive growth of less than 100 spores inoculated after primary packaging and media were subjected to worst case VHP exposure	PASS
Hold Time	Performance not affected if incubated within 72 hours of exposure to VHP sterilization	PASS
Simulated Use	Demonstrate no growth when exposed to worst-case cycles	PASS

7. 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 K171504) Class II (21 CFR 880.2800), product code FRC.