February 12, 2018

STERIS Corporation
Anthony Piotrkowski
Senior Manager, Regulatory Affairs
5976 Heisley Rd
Mentor, Ohio 44060

Re: K173634
Trade/Device Name: CELERITY 20 Steam Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 22, 2017
Received: November 24, 2017

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

510(k) Number *(if known)*
K173634

Device Name
CELERITY 20 Steam Biological Indicator

Indications for Use ***(Describe)***
The Celerity 20 Steam Biological Indicator is used for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization cycles:

- Dynamic Air Removal 270°F (132°C) 4 minutes
- Dynamic Air Removal 275°F (135°C) 3 minutes
- Gravity 250°F (121°C) 30 minutes
- Gravity 270°F (132°C) 15 minutes.

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

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
K173634
Celerity 20 Steam Biological Indicator

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: Tony Piotrkowski
Senior Manager, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 357-9198
e-mail: tpiotrko@steris.com

Submission Date: January 17, 2018

Premarket Notification Number: K173634

1. Device Name

Trade Name:	Celerity 20 Steam 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

3M Attest Super Rapid Readout Biological Indicator, K121484

3. Description of Device

The product is intended to monitor the critical parameters of steam sterilization cycles described in the indications for use by producing an optical change (signal) that is detected by the STERIS proprietary reader, Celerity 20 Steam Incubator in 20 minutes to confirm the viability of the biological indicator at the end of a steam sterilization process. The product consists of a biological organism known to be resistant to steam (*Geobacillus stearothermophilus*) and a defined nutrient media. A reporter enzyme, which is produced by the native 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 Steam Biological Indicator is used for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization cycles:

- Dynamic Air Removal 270°F (132°C) 4 minutes
- Dynamic Air Removal 275°F (135°C) 3 minutes
- Gravity 250°F (121°C) 30 minutes
- Gravity 270°F (132°C) 15 minutes.

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

5. Summary of Technical Characteristics

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

Table 5-1. Summary of SCBI Physical Description and Technological Properties

Feature	Celerity SCBI (proposed)	Attest 1492V (K121484)	Comparison
Intended Use	The Celerity 20 Steam Biological Indicator (BI) is for routine monitoring, qualification testing and product testing of the following steam sterilization processes: 270F, 4-minute dynamic air removal; 275F, 3-minnute dynamic air removal; 250 F, 30-minute gravity; 270, 15-minutes gravity. When used in conjunction with the Celerity 20 Steam Incubator, the Celerity 20 Steam Biological Indicator provides a fluorescent result within 20 minutes.	Use 3M Attest Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M Attest Auto-reader 490 to qualify or monitor dynamic air removal (prevacuum) steam sterilization cycles of 4 minutes at 270 F (132 C) and 3 minutes at 275 F (135 C). The 3M Attest Super Rapid Readout Biological Indicator 1492V provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.	Both are intended for monitoring steam sterilization cycles. The Celerity BI is claiming additional cycles compared to the predicate. Simulated use testing in sterilizers with a load under pass and fail conditions demonstrate performance of the Celerity BI in these additional cycles. The Celerity BI has a shorter claimed readout time. Reduced Incubation Time (RIT) testing per the FDA guidance demonstrates the read time is appropriate.
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Same criteria
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 mechanism
Accessories	Automated incubator / reader	Automated incubator / reader	RIT testing performed with the proposed incubator/reader.
Viable spore population	1.0 - 4.0 x 10^6 spore/SCBI	$\geq$ 1.0 x 10^6 spore/SCBI	Both proposed and predicate meet criteria of ISO 11138-3 and FDA guidance
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{132} \geq 10$ s $D_{135} \geq 8$ s	
Culture Conditions	55- 59 °C, media included in SCBI, 20-minute incubation time.	55- 59 °C, media included in SCBI, 60 minute incubation time.	RIT Testing and ISO 11138 media testing verifies performance
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Inoculated paper in plastic vial with cap and glass ampoule with recovery media in capped vial.	Similar configuration. Component testing per ISO 11138-1 Annex B demonstrates packaging is compatible with indicator and sterilization process.

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
Reduced Incubation Time (RIT) Testing	Meets FDA's requirement of > 97% alignment of the 40-minute results with the conventional incubation time of 7 days	PASS
Viable spore population	$1.0 – 4.0 \times 10^6$ spore/SCBI	$2.3 – 2.5 \times 10^6$ spore/SCBI
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{121} \geq 2.53$ min $D_{132} \geq 46$ s $D_{135} \geq 37$ s
Survival Time	Meets the longer of FDA and ISO 11138-3 requirements	121 C $\geq$ 11.11 min 132 C $\geq$ 3.42 min 135 C $\geq$ 2.77 min
Kill Time	Meets the shorter of FDA and ISO 11138-3 requirements	121 C $\leq$ 31.81 min 132 C $\leq$ 8.62 min 135 C $\leq$ 7.11 min
Carrier growth inhibition / media growth promotion	Positive growth of less than 100 spores after primary packaging and media are subject to worst case steam exposure	PASS
Hold Time	Performance not affected if incubated within 72 hours of exposure to steam sterilization	PASS
Simulated Use	Demonstrate growth when exposed to abbreviated cycle and all kill in a full cycle	Abbreviated cycle – growth Full cycle – no growth

7. Conclusion

The Celerity 20 Steam Biological Indicator has met the established performance criteria. The conclusions drawn from the nonclinical tests performed demonstrate the subject device is as safe, as effective, and performs as well or better than the legally marketed predicate device, K121424 Class II (21 CFR 880.2800, Product code FRC).