January 8, 2021

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

Re: K202721
Trade/Device Name: Celerity 20 Steam Biological Indicator for IUSS
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: December 10, 2020
Received: December 11, 2020

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.
Acting 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)*
K202721

Device Name
Celerity 20 STEAM Biological Indicator for IUSS

Indications for Use *(Describe)*

The Celerity 20 STEAM Biological Indicator for IUSS is used for monitoring and qualification testing of the following steam sterilization cycles:
Gravity 270°F (132°C) 3 minutes
Gravity 270°F (132°C) 10 minutes
Gravity 275°F (135°C) 3 minutes
Gravity 275°F (135°C) 10 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
Celerity 20 Steam Biological Indicator for IUSS

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
Director, Regulatory Affairs

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

Submission Date: January 8, 2021

Premarket Notification number: K202721

1. Device Name

Trade Name:	Celerity 20 Steam Biological Indicator for IUSS
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 1491 Super Rapid Readout Biological Indicator, K103277

3. Reference Device

Celerity 20 Steam Biological Indicator, cleared under K173634 and modified under K181686

4. 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.

5. Intended Use/ Indications for Use

The Celerity 20 STEAM Biological Indicator for IUSS is used for monitoring and qualification testing of the following steam sterilization cycles:

- Gravity 270°F (132°C) 3 minutes
- Gravity 270°F (132°C) 10 minutes
- Gravity 275°F (135°C) 3 minutes
- Gravity 275°F (135°C) 10 minutes.

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

6. Summary of Technical Characteristics

A comparison of technical characteristics of the proposed device to the predicate are summarized in **Table 5-1**.

Table 5-1. Proposed vs Predicate Physical Description and Technological Properties

Feature	Celerity SCBI for IUSS (proposed)	K103277 Attest 1491 (Predicate)	Comparison
Intended Use	The Celerity 20 STEAM Biological Indicator for IUSS is used for monitoring and qualification testing of the following steam sterilization cycles: Gravity 270°F (132°C) 3 minutes Gravity 270°F (132°C) 10 minutes Gravity 275°F (135°C) 3 minutes Gravity 275°F (135°C) 10 minutes. When used in conjunction with the Celerity STEAM Incubator, the Incubator provides a fluorescent result within 20 minutes.	Use 3M Attest 1491 Super Rapid Read Biological Indicator in conjunction with the 3M Attest Auto-reader 490 to monitor the cycles below. Gravity Displacement IUSS (Flash): 270°F(132°C) 3 minutes; 270°F(132°C) 10 minutes; 275°F(135°C) 3 minutes; 275°F(135°C) 10 minutes. The 3M Attest 1491 Super Rapid Readout Biological Indicator provides a final fluorescent result in 30 minutes. An optional visual pH color change result is observed in 24 hours.	Both are intended for monitoring the same steam sterilization 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 the FDA guidance on Biological Indicator 510(k)
Resistance	$D_{132} \geq 10$ 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, 30 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.

A comparison of technical characteristics of the proposed device to the predicate are summarized in **Table 5-2**.

Table 5-2. Proposed vs Reference Physical Description and Technological Properties

Feature	Celerity SCBI for IUSS (proposed)	K173634 Celerity 20 Steam BI (Reference)	Comparison
Intended Use	The Celerity 20 STEAM Biological Indicator for IUSS is used for monitoring and qualification testing of the following steam sterilization cycles: Gravity 270°F (132°C) 3 minutes Gravity 270°F (132°C) 10 minutes Gravity 275°F (135°C) 3 minutes Gravity 275°F (135°C) 10 minutes. When used in conjunction with the Celerity STEAM Incubator, the Incubator provides a fluorescent result within 20 minutes.	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.	Both are intended for monitoring steam sterilization cycles. The Celerity BI for IUSS is specifically for gravity IUSS cycles. Testing is provided in this 510(k) to demonstrate suitable performance in gravity IUSS cycles.
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Identical
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	Identical
Accessories	Automated incubator / reader	Automated incubator / reader	Both use the same reader
Viable spore population	1.0 - 4.0 x 10^6 spore/SCBI	1.0 - 4.0 x 10^6 spore/SCBI	Identical
Resistance	$D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	Identical at the two temperatures for which the proposed device is indicated
Culture Conditions	55- 59 °C, media included in SCBI, 20-minute incubation time.	55- 59 °C, media included in SCBI, 20-minute incubation time.	Identical
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, cap with recovery media.	Identical

7. Summary of Nonclinical Tests

Performance testing 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 20-minute results with the conventional incubation time of 7 days	PASS
Viable spore population	1.0 – 4.0 x 10^6 spore/SCBI	PASS
Resistance	$D_{132} \geq 10$ s $D_{135} \geq 8$ s	PASS
Survival Time	Meets FDA requirements	132 C $\geq$ 1 min 135 C $\geq$ 0.667 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 8 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
Shelf-life	Population, resistance, RIT and media must meet above criteria at each stability time point	PASS at 3 months (ongoing)

7. Conclusion

The conclusion drawn from the nonclinical tests performed demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K103277 Class II (21 CFR 880.2800, Product code FRC).