



FDA U.S. FOOD & DRUG
ADMINISTRATION

STERIS Corporation
Tony Piotrkowski
Senior Regulatory Affairs Manager
5960 Heisley Rd
Mentor, Ohio 44060

Re: K181686
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: June 25, 2018
Received: June 26, 2018

Dear Tony 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,

Clarence W. Murray lii III -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

Indications for Use

510(k) Number (if known)

K181686

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.

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**510(k) Summary
For
Celerity 20 Steam Biological Indicator**

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Submission Date: July 18, 2018

Premarket Notification Number: K181686

Celerity 20 Steam Biological Indicator

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**

Celerity 20 Steam Biological Indicator, K173634

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 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.

Celerity 20 Steam Biological Indicator

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 20 Steam SCBI (modified)	Celerity 20 Steam SCBI Predicate (K173634)	Comparison
Intended Use	<p>The Celerity 20 Steam Biological Indicator is used for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization cycles:</p> <ul style="list-style-type: none"> • 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. <p>When used in conjunction with the Celerity™ Steam Incubator, the Incubator provides a fluorescent result within 20 minutes.</p>	<p>The Celerity 20 Steam Biological Indicator is used for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization cycles:</p> <ul style="list-style-type: none"> • 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. <p>When used in conjunction with the Celerity™ Steam Incubator, the Incubator provides a fluorescent result within 20 minutes.</p>	Identical
Indicator organism	> 90% similarity to ATCC 7953 <i>Geobacillus stearothermophilus</i>	> 90% similarity to ATCC 7953 <i>Geobacillus stearothermophilus</i>	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	Identical
Viable spore population	1.0 - 4.0 x 10 ⁶ spore/SCBI	1.0 - 4.0 x 10 ⁶ spore/SCBI	Identical
Resistance	D ₁₂₁ ≥ 1.5 min D ₁₃₂ ≥ 10 s D ₁₃₅ ≥ 8 s	D ₁₂₁ ≥ 1.5 min D ₁₃₂ ≥ 10 s D ₁₃₅ ≥ 8 s	
Survival Time	Meets the longer of FDA and ISO 11138-3 requirements	Meets the longer of FDA and ISO 11138-3 requirements	Identical
Kill Time	Meets the shorter of FDA and ISO 11138-3 requirements	Meets the shorter of FDA and ISO 11138-3 requirements	Identical
Hold time	Up to 72 h	Up to 72 h	Identical
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	Positive growth of less than 100 spores after primary packaging and media are subject to worst case steam exposure	Identical

Celerity 20 Steam Biological Indicator

Feature	Celerity 20 Steam SCBI (modified)	Celerity 20 Steam SCBI Predicate (K173634)	Comparison
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
Shelf Life	10 months	10 months	Shelf-life testing is ongoing
Cap label	Single-ply label on cap edge Process indicator on label	Two-ply label on cap top Process indicator on label	Same adhesive, process indicator ink and substrate different format and location

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 no growth when exposed to a full cycle	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, K173634 Class II (21 CFR 880.2800, Product code FRC).