February 12, 2018

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

Re: K173670
Trade/Device Name: CELERITY 20 Steam Incubator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 29, 2017
Received: November 30, 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)*
K173670

Device Name
Celerity 20 Steam Incubator

Indications for Use *(Describe)*
Use the Celerity 20 Steam Incubator to incubate and automatically read Celerity 20 Steam Biological Indicators at 57 °C for 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
K173670
Celerity 20 Steam Incubator

Sponsor Facility

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Submission Date: January 17, 2018

Premarket Notification Number: K173670

1. Device Name

Trade Name:	Celerity 20 Steam Incubator
Common/usual Name:	Incubator/Reader (accessory to Biological Indicator)
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

2. Predicate Device

K171587 - VERIFY Incubator for Assert VH2O2 Self-Contained Biological Indicator, (since renamed Celerity 20 HP Incubator)

3. Description of Device

The Celerity 20 Steam Incubator (Incubator) is an incubator/reader designed for use specifically with the Celerity 20 Steam Biological Indicator (BI), subject of a concurrent 510(k) currently under review. The incubator/reader provides a constant temperature range to allow for activation and outgrowth of *Geobacillus stearothermophilus* leading to production of a fluorescent moiety. The presence of an increasing fluorescence signal due to increasing concentrations of this fluorescent moiety in the BI is detected by the incubator/reader and indicates the presence of viable test microorganisms.

4. Intended Use/ Indications for Use

Use the Celerity 20 Steam Incubator to incubate and automatically read Celerity 20 Steam Biological Indicators at 57 °C for 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 Incubator Physical Description and Technological Properties

Feature	Celerity Steam Incubator (proposed)	VERIFY Incubator (K71587) Predicate	Comparison
Intended Use	Use the Celerity 20 Steam Incubator to incubate and automatically read Celerity 20 Steam Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Use the VERIFY Incubator for Assert VH2O2 Self Contained Biological Indicators (Incubator) to incubate and automatically read VERIFY Assert VH2O2 Self-Contained Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Identical except for the BI they are meant to read. Testing with the Celerity 20 Steam BI, included in the submission, demonstrates proper performance.
Basis of Readout	Photodiode detects fluorescence produced by enzymatic activity that results from growing biological indicator organisms	Photodiode detects fluorescence produced by enzymatic activity that results from growing biological indicator organisms	Same
Incubation Temperature Range	55 - 60 °C	55 - 60 °C	Same
Voltage Range	90 to 264 VAC with 12 VDC conversion.	90 to 264 VAC with 12 VDC conversion.	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
Maintenance of Incubation Temperature	Maintain 55-60 °C for a minimum of 20 minutes (incubation time of Celerity 20 Steam BI)	PASS
Qualification testing with Celerity 20 Steam BI	20-minute fluorescent read meets >97% alignment with 7-day growth results per FDA guidance on reduced incubation time.	PASS

Test	Acceptance Criteria	Conclusion
Qualification testing with Celerity 20 Steam BI	• Pass testing with BI exposed to full cycle exposure and negative growth result in incubator • Fail testing with BI exposed in abbreviated cycle exposure and positive result in incubator	PASS PASS
Alarm, LED and Print function Test	Demonstrate proper function of alarms, LED and print outputs	PASS

7. Conclusion

The Celerity 20 Steam Incubator 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 VERIFY Incubator for Assert VH2O2 Self-Contained Biological Indicator cleared in K171587 (21 CFR 880.2800, Product code FRC).