May 14, 2019

Steris Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K190297
Trade/Device Name: Celerity HP Incubator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: April 16, 2019
Received: April 17, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

David Krause, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190297

Device Name

Celerity HP Incubator

Indications for Use *(Describe)*

Use the Celerity HP Incubator to incubate and automatically read Celerity 20 HP 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
Celerity HP Incubator
K190297

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: Anthony Piotrkowski

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

Submission Date: February 8, 2019

1. Device Name

Trade Name:	Celerity HP 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 Indicators (name changed to Celerity HP Incubator after clearance)

3. Reference Device

K173670 - Celerity 20 Steam Incubator

4. Description of Device

Celerity HP Incubator (Incubator) is an incubator/reader designed for use specifically with the Celerity 20 HP Biological Indicator (BI). The incubator/reader provides a constant temperature range to allow for activation and outgrowth of *Geobacillus stearothermophilus* which is detected by an enzyme that cleaves the a substrate 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.

5. Intended Use/ Indications for Use

Use the Celerity HP Incubator to incubate and automatically read Celerity 20 HP Biological Indicators at 57 °C for a fluorescent result within 20 minutes.

6. Summary of Technical Characteristics

Comparisons of technical characteristics versus the predicate and reference devices are summarized in **Tables 5-1 and 5-2** respectively.

Table 5-1 Summary of Incubator Physical Description and Technological Properties vs Predicate

Feature	VERIFY Incubator for Assert VH2O2 SCBI (predicate K171587)	Celerity HP Incubator (modified)	Comparison
Intended Use	Use the Celerity HP Incubator to incubate and automatically read VERIFY Assert VH2O2 Self-Contained Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Use the Celerity HP Incubator to incubate and automatically read Celerity HP Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Same indications for use – the name of the incubator has changed.
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	100-240 VAC with 12 VDC conversion.	100-240 VAC with 12 VDC conversion.	Same
Test capacity	8 wells	8 wells	Same
Calibration	Factory calibration – no calibration by customer	Factory calibration – no calibration by customer	Same
Incubation Time	20 minutes	20 minutes	Same
Fluorescence Detection	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the SCBI's media. The emitted light is detected by a photodiode.	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the SCBI's media. The emitted light is detected by a photodiode.	Same
Compliance	Electrical Safety and EMC Testing • IEC 61010-1 (2010) Third Ed • IEC 61010-2-010 (2013) Third Ed Electromagnetic compatibility • USA Title 47, Code of Federal Regulations (2007) for: ○ Radiated Emissions (FCC Part 15, Subpart B, Class A) ○ Conducted Emissions (FCC Part 15, Subpart B, Class A) • IEC 61326:2013 - • EN 55011:2009, Inc. A1:2010 • EN 61000-3-2:2006, Inc. A1:2009 and A2:2009 EN 61000-3-3:2013	Electrical Safety and EMC Testing • IEC 61010-1 (2010) Third Ed • IEC 61010-2-010 (2013) Third Ed Electromagnetic compatibility • USA Title 47, Code of Federal Regulations (2007) for: ○ Radiated Emissions (FCC Part 15, Subpart B, Class A) ○ Conducted Emissions (FCC Part 15, Subpart B, Class A) • IEC 61326:2013 - • EN 55011:2009, Inc. A1:2010 • EN 61000-3-2:2006, Inc. A1:2009 and A2:2009 EN 61000-3-3:2013	Same
Indication of Results	Positive – audible alarm, visual LED lights and screen Negative – no alarm, visual indication with LED lights and LCD screen User must acknowledge results	Positive – audible alarm, visual LED lights and screen Negative – no alarm, visual indication with LED lights and LCD screen User must acknowledge results	Same

Feature	VERIFY Incubator for Assert VH2O2 SCBI (predicate K171587)	Celerity HP Incubator (modified)	Comparison
System Operation	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 57ºC. The measurement of fluorescence is initiated by placement of a VERIFY Assert SCBI into any of the incubation wells and pressing the adjacent "ACTION" button. When an SCBI is placed into a well, the auto-reader detects its presence. Upon pressing the button associated with that well, a blinking yellow light indicates that incubation is in process and the read initiated. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific SCBI. Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD.	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 57ºC. The measurement of fluorescence is initiated by placement of a VERIFY Assert SCBI into any of the incubation wells and pressing the adjacent "ACTION" button. When an SCBI is placed into a well, the auto-reader detects its presence. Upon pressing the button associated with that well, a blinking yellow light indicates that incubation is in process and the read initiated. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific SCBI. Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD.	Same

Table 5-2 Summary of Incubator Physical Description and Technological Properties vs. Reference Device

Feature	Celerity Steam Incubator (Reference K173670)	Celerity HP Incubator (modified)	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 Celerity HP Incubator to incubate and automatically read Celerity HP Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Same operating temperature and read time

Feature	Celerity Steam Incubator (Reference K173670)	Celerity HP Incubator (modified)	Comparison
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.	100-240 VAC with 12 VDC conversion.	Proposed within range of reference
Test capacity	8 wells	8 wells	Same
Calibration	Factory calibration – no calibration by customer	Factory calibration – no calibration by customer	Same
Incubation Time	20 minutes	20 minutes	Same
Fluorescence Detection	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the SCBI's media. The emitted light is detected by a photodiode.	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the SCBI's media. The emitted light is detected by a photodiode.	Same
Compliance	Electrical Safety and EMC Testing • IEC 61010-1 (2010) Third Ed • IEC 61010-2-010 (2013) Third Ed Electromagnetic compatibility • USA Title 47, Code of Federal Regulations (2007) for: ○ Radiated Emissions (FCC Part 15, Subpart B, Class A) ○ Conducted Emissions (FCC Part 15, Subpart B, Class A) • IEC 61326:2013 - • EN 55011:2009, Inc. A1:2010 • EN 61000-3-2:2006, Inc. A1:2009 and A2:2009 • EN 61000-3-3:2013	Electrical Safety and EMC Testing • IEC 61010-1 (2010) Third Ed • IEC 61010-2-010 (2013) Third Ed Electromagnetic compatibility • USA Title 47, Code of Federal Regulations (2007) for: ○ Radiated Emissions (FCC Part 15, Subpart B, Class A) ○ Conducted Emissions (FCC Part 15, Subpart B, Class A) • IEC 61326:2013 - • EN 55011:2009, Inc. A1:2010 • EN 61000-3-2:2006, Inc. A1:2009 and A2:2009 EN 61000-3-3:2013	Same
Indication of Results	Positive – audible alarm, visual LED lights and screen Negative – no alarm, visual indication with LED lights and LCD screen User must acknowledge results	Positive – audible alarm, visual LED lights and screen Negative – no alarm, visual indication with LED lights and LCD screen User must acknowledge results	Same

Feature	Celerity Steam Incubator (Reference K173670)	Celerity HP Incubator (modified)	Comparison
System Operation	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 57ºC. The measurement of fluorescence is initiated by placement of a VERIFY Assert SCBI into any of the incubation wells and pressing the adjacent "ACTION" button. When an SCBI is placed into a well, the auto-reader detects its presence. Upon pressing the button associated with that well, a blinking yellow light indicates that incubation is in process and the read initiated. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific SCBI. Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD.	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 57ºC. The measurement of fluorescence is initiated by placement of a VERIFY Assert SCBI into any of the incubation wells and pressing the adjacent "ACTION" button. When an SCBI is placed into a well, the auto-reader detects its presence. Upon pressing the button associated with that well, a blinking yellow light indicates that incubation is in process and the read initiated. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific SCBI. Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD.	Same

7. Summary of Nonclinical Tests

Performance testing was performed to verify that the subject device will meet the acceptance criteria of the performance test shown in **Table 5-3** below.

Table 5-3. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
Electrical Safety - General	Conform with UL 61010-1 3rd Edition	PASS
Electrical Safety – Heating Equipment	Conform with UL 61010-2-010:2015 Ed.3	PASS
Electromagnetic Compatability	Conform with IEC 61326-1:2012 and FCC 47 CFR Part 15	PASS
Alarm, LED and Print function Test	Demonstrate proper function of alarms, LED and print outputs	PASS

8. Conclusion

The Celerity HP Incubator has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical test performed, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device, VERIFY® Incubator for Assert™ VH2O2 Self-Contained Biological Indicators, K171587, Class II (21 CFR 880.2800, Product code FRC).