DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 22, 2017

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

Re: K171587
Trade/Device Name: VERIFY Incubator for Assert VH2O2 Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: July 31, 2017
Received: August 1, 2017

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Lori Wiggins
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171587

Device Name
VERIFY Incubator for Assert VH2O2 Self Contained Biological Indicators

Indications for Use *(Describe)*
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.

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
VERIFY® Incubator for Assert™ VH2O2 Self-Contained Biological Indicators

Sponsor Facility

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Manufacturing Facility

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Submission Date: August 21, 2017

Premarket Notification Number: K171587

1. Device Name

Trade Name:	VERIFY® Incubator for Assert™ VH2O2 Self Contained Biological Indicators
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

3M Attest 390 Auto-reader, K123546

Reference Device: VERIFY® Incubator for Assert™ Self Contained Biological Indicators, K163587

3. Description of Device

VERIFY® Incubator for Assert™ VH2O2 Self Contained Biological Indicators (Incubator) is an incubator/reader designed for use specifically with the VERIFY Assert VH2O2 Self-Contained Biological Indicator (SCBI), subject of a concurrent submission, K171504, currently under review. The incubator/reader provides a constant temperature range to allow for activation and outgrowth of *Geobacillus stearothermophilus* leading to production of an endogenous fluorescent moiety. The presence of an increasing fluorescence signal due to increasing concentrations of this fluorescent moiety in the SCBI is detected by the incubator/reader and indicates the presence of viable test microorganisms

4. Intended Use/ Indications for Use

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.

5. 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 (proposed)	Attest 390 (K123546) Predicate	Comparison
Intended Use	Use the VERIFY Incubator for Assert VH2O2 Self Contained Biological Indicators to incubate and automatically read VERIFY Assert VH2O2 Self-Contained Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	The 3M Attest 390 Auto-reader is designed to incubate and automatically read the 3M Attest Rapid readout Biological indicators for Steam 1291, 1292, at 60 °C for a final fluorescent result at 1 hour for 1291 and 3 hours for 1292.	Both are intended for incubation and automatic reading of specific self-contained biological indicators.
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	60 ± 2 °C	Both operate within the growth temperature range of *Geobacillus stearothermophilus*
Voltage Range	100-240 VAC with 12 VDC conversion.	100-240 VAC with 12 VDC conversion.	Same
Test capacity	8 wells	10 wells	Both can accommodate multiple samples
Calibration	Factory calibration – no calibration by customer	Factory calibration – no calibration by customer	Same
Incubation Time	20 minutes	1 hour (1291), 3 hours (1292)	Reduced incubation time testing, in accordance with FDA guidance, confirms read time
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

Feature	VERIFY Incubator for Assert VH2O2 SCBI (proposed)	Attest 390 (K123546) Predicate	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 measurement of fluorescence is initiated by placement of an Attest SCBI into any of the incubation wells. The reader/incubator wells are color-coded to match the color of the top of the SCBIs. The incubator block may be color coded. When a BI is placed into a well, its presence is detected. The LCD screen below the SCBI shows the time remaining to complete the incubation period. Detection of a positive result is indicated by a '+' sign on the LCD screen, accompanied by an audible alarm. A positive result is indicative of a sterilization cycle failure. The alarm must be muted by the operator when a positive result is obtained. Pressing the mute button disables the alarm only for the specific SCBI which was just identified as positive. Should another BI become "positive", the alarm will again sound. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a '- 'sign on the LCD screen.	Both have similar modes of operation only one type of biological indicator is intended for use with the proposed device so no color coding is required and both alarm for a positive BI.

Feature	VERIFY Incubator for Assert VH2O2 SCBI (proposed)	Attest 390 (K123546) Predicate	Comparison
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 (if enabled), "+" indication on LCD panel, and flashing of LCD panel backlighting Negative – no alarm, "-"indication on LCD panel	Similar Indication of Results

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 (2001) Second Ed
		• IEC 61010-2-010 (2003) Second Ed
		Electromagnetic compatibility
		• USA Title 47, Code of Federal Regulations (2009) for:
		  • Radiated Emissions (FCC Part 15, Subpart B, Class A)
		  • Conducted Emissions (FCC Part 15, Subpart B, Class A)
		• IEC 61326:
			Both meet relevant electrical standards for safety, emissions and compatibility that were active at time of submission.

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

Feature	VERIFY Incubator for Assert SCBI (proposed)	VERIFY Incubator for Assert SCBI K163587 (Reference)	Comparison
Intended Use	Use the VERIFY Incubator for Assert VH2O2 Self Contained Biological Indicators to incubate and automatically read VERIFY Assert VH2O2 Self-Contained Biological Indicators at 57 °C for a fluorescent result within 20 minutes.	Use the VERIFY® Incubator for Assert™ Self Contained Biological Indicators SCBI to incubate and automatically read VERIFY Assert Self-Contained Biological Indicators at 57 °C for a fluorescent result within 40 minutes.	Both are intended for incubation and automatic reading of specific self-contained biological indicators.
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	40 minutes	Reduced incubation time testing, in accordance with FDA guidance, is confirms read time.
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

Feature	VERIFY Incubator for Assert SCBI (proposed)	VERIFY Incubator for Assert SCBI K163587 (Reference)	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

Feature	VERIFY Incubator for Assert SCBI (proposed)	VERIFY Incubator for Assert SCBI K163587 (Reference)	Comparison
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

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

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-3** below.

Table 5-3. 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 Verify Assert SCBI as stated in K162701)	PASS

Test	Acceptance Criteria	Conclusion
Qualification testing with Verify Assert SCBI	20-minute fluorescent read meets >97% alignment with 7-day growth results per FDA guidance on reduced incubation time.	PASS
Qualification testing with Verify Assert SCBI	Pass testing with SCBI exposed to full cycle exposure and negative growth result in incubator	PASS
	Fail testing with SCBI exposed in abbreviated cycle exposure and positive result in incubator	PASS
Alarm, LED and Print function Test	Demonstrate proper function of alarms, LED and print outputs	PASS

7. Conclusion

The VERIFY Incubator for VH2O2 Assert Self-Contained Biological Indicator has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as the legally marketed predicate device, K123546, Class II (21 CFR 880.2800, Product code FRC).