DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 22, 2017

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

Re: K171504
Trade/Device Name: VERIFY 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)*
K171504

Device Name
VERIFY Assert VH2O2 Self-Contained Biological Indicator

Indications for Use *(Describe)*
The VERIFY Assert VH2O2 Self-Contained Biological Indicator is used for routine monitoring, and qualification of Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX, and 60 Low Temperature Sterilizers in healthcare facilities.

When used in conjunction with the VERIFY Incubator for Assert VH2O2 SCBI, the VERIFY Assert Self-Contained Indicator 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
VERIFY Assert VH2O2 Self-Contained Biological Indicator

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Submission Date: August 21, 2017

Premarket Notification Number: K171504

1. Device Name

Trade Name: VERIFY Assert VH2O2 Self-Contained 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

VERIFY® V24 Self-Contained Biological Indicator, K140499

Reference Devices

3M Attest™ Rapid Readout Biological Indicator 1295, K160546

3. Description of Device

The product is intended to monitor the vapor phased hydrogen peroxide sterilization cycles described in the indications for use. It produces an optical change (signal) that is detected by the STERIS proprietary reader, Incubator for VERIFY Assert VH2O2 Self-Contained Biological Indicator, within 20 minutes to confirm the viability of the biological indicator at the end of a sterilization process. The product consists of *Geobacillus stearothermophilus* spores and a defined nutrient media in a plastic vial. A reporter enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.

4. Intended Use/ Indications for Use

The VERIFY Assert VH2O2 Self-Contained Biological Indicator is used for routine monitoring, and qualification of Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX, and 60 Low Temperature Sterilizers in healthcare facilities.

When used in conjunction with the VERIFY Incubator for Assert VH2O2 SCBI, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 20 minutes.

5. Summary of Technical Characteristics

A comparison of technical characteristics versus the predicate is summarized in **Table 5-1** and versus the reference device in **Table 5-2.**

Table 5-1 SCBI Physical Description and Technological Properties vs the Predicate Device

Feature	Assert VH2O2 SCBI (proposed)	VERIFY V24 SCBI Predicate (K140499)	Comparison
Intended Use	The VERIFY Assert VH2O2 Self-Contained Biological Indicator is used for routine monitoring, and qualification of Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX, and 60 Low Temperature Sterilizers in healthcare facilities. When used in conjunction with the VERIFY Incubator for Assert VH2O2 SCBI, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 20 minutes.	The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the Lumen, Non Lumen and Flexible cycles of V-PRO® Low Temperature Sterilization Systems.	Intended cycles are the same for both predicate and proposed. The proposed indications for use include information about the incubator/reader and read time that are supported through testing in accordance with FDA guidance for BI 510(k).
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same
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.	Visual detection of growth based on media color change in the presence of surviving indicator organisms.	Both devices indicate survival of indicator organisms after sterilization. The mechanism of the proposed device is more similar to the reference device (see table 5-2). Resistance testing and simulated use testing demonstrate appropriate monitoring of indicated sterilization cycles.
Accessories	Automated incubator / reader	None	This accessory is more similar to the reference device (see table 5-2) than to the predicate device. RIT testing and simulated use testing demonstrate appropriate monitoring of indicated sterilization cycles.

Feature	Assert VH2O2 SCBI (proposed)	VERIFY V24 SCBI Predicate (K140499)	Comparison
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	2.0 – 3.4 x 10^6 spore/BI	Both contain greater than 10^6 spores/BI.
Resistance characteristics	Resistance @ 9.1 mg/L H_2O_2: • D-value > 3 sec • Survival Time ≥ 4 sec • Kill Time ≤ 6 min	Resistance @ 2.7 mg/L H_2O_2: • D-value 4.0 – 8.0 sec • Survival Time 4 - 30 sec • Kill Time ≤ 16 min	Resistance testing for proposed device at a higher H2O2 concentration. Simulated use testing verifies suitability for use in claimed cycles.
Culture Conditions	55- 59 °C, media included in SCBI, 20-minute incubation time.	55- 59 °C, media included in SCBI, 24h incubation time.	RIT Testing and ISO 11138-1 media testing verifies performance
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, glass ampule with recovery media.	Similar configuration. Component testing per ISO 11138-1 Annex B demonstrates packaging is compatible with indicator and sterilization process.
Process indicator	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	Same
Shelf-life	Currently 3 months Target of 13 months	18 months	Real-time testing ongoing

Table 5-2 SCBI Physical Description and Technological Properties vs the Reference Device

Feature	Assert VH2O2 SCBI (proposed)	Attest 1295 Reference (K160546)	Comparison
Intended Use	The VERIFY Assert VH2O2 Self-Contained Biological Indicator is used for routine monitoring, and qualification of Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX, and 60 Low Temperature Sterilizers in healthcare facilities. When used in conjunction with the VERIFY Incubator for Assert VH2O2 SCBI, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 20 minutes.	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M Attest™ Auto reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles) and 100NX (Standard, Flex, Express and Duo cycles) systems.	Intended cycles for both reference and proposed devices include V-PRO sterilizer cycles. Both require an automated incubator/reader for results.
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same

Feature	Assert VH2O2 SCBI (proposed)	Attest 1295 Reference (K160546)	Comparison
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 of action
Accessories	Automated incubator / reader	Automated incubator / reader	This accessory is similar to the reference. RIT testing and simulated use testing demonstrate appropriate monitoring of indicated sterilization cycles.
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	≥ 1.0 x 10^6 spore/BI	Both contain greater than 10^6 spores/BI.
Resistance characteristics	Resistance @ 9.1 mg/L H_2O_2: • D-value > 3 sec • Survival Time ≥ 4 sec • Kill Time ≤ 6 min	Resistance @ 10 mg/L H_2O_2: • D-value > 1 sec • Survival Time ≥ 5 sec • Kill Time = 7 min	Resistance values are similar for both devices. Simulated use testing verifies suitability for use in claimed cycles.
Culture Conditions	55- 59 °C, media included in SCBI, 20-minute incubation time.	60 +/- 2 °C; media included in SCBI, 4-hour incubation time.	RIT Testing and ISO 11138-1 media testing verifies performance
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Inoculation on plastic disc within vial, ampoule of recovery medium.	Similar configuration. Component testing per ISO 11138-1 Annex B demonstrates packaging is compatible with indicator organism and sterilization process.
Process indicator	VERIFY V-PRO Chemical Indicator (K091174); magenta to yellow color change.	H2O2 sensitive ink; appears blue until processed, then appears pink	Both contain a VH2O2 CI to distinguish processed SCBI from unprocessed SCBI.
Shelf-life	Currently 3 months Target of 13 months	18 months	Real-time testing ongoing

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
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

Test	Acceptance Criteria	Conclusion
Resistance	D-value > 3 sec	PASS
Survival Time	Survival Time ≥ 4 sec	PASS
Kill Time	Kill Time ≤ 6 min	PASS
Carrier growth inhibition / media growth promotion	Positive growth of less than 100 spores after primary packaging and media are subject to worst case VHP exposure	PASS
Hold Time	Performance not affected if incubated within 72 hours of exposure to VHP sterilization	PASS
Simulated Use	Demonstrate no growth when exposed to worst-case cycles	PASS

7. Conclusion

The VERIFY Assert Self-Contained Biological Indicator has met the established performance criteria. The results of the studies demonstrate that the biological indicator performs as intended, and based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as the legally marketed predicate device, K140499, Class II (21 CFR 880.2800, Product code FRC).