DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 28, 2017

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

Re: K170070
Trade/Device Name: VERIFY™ Assert™ STEAM Process Challenge Device for Gravity Cycles
Regulation Number: 21 CFR 880.2800 (b)
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: March 28, 2017
Received: March 29, 2017

Dear Mr. 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.

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" (21CFR 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170070

Device Name
VERIFY Assert STEAM Process Challenge Device for Gravity Cycles

Indications for Use *(Describe)*

The VERIFY™ ASSERT™ STEAM Process Challenge Device for Gravity Cycles is used for qualification, routine microbial monitoring, and cycle monitoring of steam sterilizers.

The validated steam sterilization cycles include:
• 250°F (121°C) 30-minute gravity
• 270°F (132°C) 15-minute gravity

The VERIFY Assert Self-Contained Indicator within the Process challenge device must be used with the VERIFY Incubator for Assert Self Contained Biological Indicators. When used in conjunction with the VERIFY Incubator for Assert Self Contained Biological Indicators, the VERIFY Assert Self-Contained Indicator within the Process challenge device provides a fluorescent result within 40 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™ STEAM Process Challenge Device for Gravity Cycles

Sponsor Facility

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Manufacturing Facility

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Submission Date: April 28, 2017

Premarket Notification Number: K170070

1. Device Name

Trade Name:	VERIFY™ Assert™ STEAM Process Challenge Device for Gravity Cycles
Common/usual Name:	Biological Indicator Pack (PCD)
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

2. Predicate Device

3M Attest Super Rapid 5 Steam-Plus Challenge Pack K121593

3. Description of Device

The VERIFY™ Assert™ STEAM Process Challenge Device for Gravity Cycles (Gravity PCD), contains a VERIFY Assert Self-Contained Biological Indicator (SCBI) and a steam chemical integrator, sealed within a plastic tray with foil cover. The tray has a molded channel which serves as the tortuous pathway for air removal/steam penetration during steam sterilization. The PCD is designed and validated to be equivalent to the standard 16-towel test pack described in ANSI/AAMI ST79.

4. Intended Use/ Indications for Use

The VERIFY™ ASSERT™ STEAM Process Challenge Device for Gravity Cycles is used for qualification, routine microbial monitoring, and cycle monitoring of steam sterilizers.

The validated steam sterilization cycles include:

- 250°F (121°C) 30-minute gravity
- 270°F (132°C) 15-minute gravity

The VERIFY Assert Self-Contained Indicator within the Process challenge device must be used with the VERIFY Incubator for Assert Self Contained Biological Indicators. When used in conjunction with the VERIFY Incubator for Assert Self Contained Biological Indicators, the VERIFY Assert Self-Contained Indicator within the Process challenge device provides a fluorescent result within 40 minutes.

5. Summary of Technical Characteristics

A comparison of technical characteristics of the PCD are in **Table 3-1**.

Table 3-1 Summary of PCD Physical Description and Technological Properties

Feature	Assert Gravity PCD (proposed)	Attest 41482V (K121593) Predicate	Comparison
Intended Use	The VERIFY™ Assert™ STEAM Process Challenge Device (PCD) is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers. 270F (132°C), 15-minute gravity; 250F (121°C), 30-minute gravity When used in conjunction with the VERIFY Incubator for Assert Self Contained Biological Indicators, the VERIFY Assert Self-Contained Indicator within the Process challenge device provides a fluorescent result within 40 minutes	Use 3M Attest Super Rapid 5 Steam-Plus Challenge Pack in conjunction with the 3M Attest Auto-reader 490 to qualify or monitor dynamic air removal (prevacuum) steam sterilization cycles of 4 minutes at 270 F (132 C) and 3 minutes at 275 F (135 C). The 3M Attest Super Rapid Readout Biological Indicator contained within the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.	Both are intended for monitoring steam sterilization cycles. Testing to demonstrate performance in the claimed cycles has been completed.
General Design	Indicators are sealed in plastic tray with channel to limit steam penetration/air removal.	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Both the devices are contained in a steam barrier. Testing to demonstrate equivalence has been completed.
Biological Indicator	Verify Assert Self Contained Biological Indicator (40-minute fluorescent result)	Attest 1492V Biological Indicator (1-hour fluorescent result)	Both contain 510(k)-cleared Biological Indicators with rapid fluorescent results.
Chemical Integrator	Non-commercial Chemical Integrator	SteriGage Chemical Integrator	Both contain chemical integrators
Means to distinguish processed PCD from unprocessed	Proposed device's internal integrator is visible through the pack.	External process indicator. Yellow to brown color change when exposed to steam	Both have a means to distinguish processed PCD from unprocessed

A comparison of technical characteristics BI components of the PCD are in Table 3-2.

Table 5-2 Summary of SCBI Components of the PCD Physical Description and Technological Properties

Feature	Assert SCBI (K162701)	Attest 1492V (K121484)	Comparison
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Same criteria
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
Accessories	Automated incubator / reader (K1635870 • 40 minute incubation time • Holds temperature range throughout incubation time.	Automated incubator / reader • 60 minute incubation time • Holds temperature range throughout incubation time.	RIT testing performed with the proposed incubator/reader cleared uner K163587. Inubator readers meet criterion of FDA BI 510(k) guidance.
Viable spore population	1.0 - 4.0 x 10^6 spore/SCBI	$\geq$ 1.0 x 10^6 spore/SCBI	Both proposed and predicate meet criteria of ISO 11138-3 and FDA guidance
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{132} \geq 10$ s $D_{135} \geq 8$ s	
Culture Conditions	55- 59 °C, media included in SCBI, 40 minute incubation time.	55- 59 °C, media included in SCBI, 60 minute incubation time.	RIT Testing and ISO 11138 media testing verifies performance
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Inoculated paper in plastic vial with cap and glass ampoule with recovery media in capped vial.	Similar configuration. Component testing per ISO 11138-1 Annex B demonstrates packaging is compatible with indicator and sterilization process..

Any differences between the predicate and proposed device as noted above are addressed through testing summarized below or submitted as part of the cleared 510(k): K162701 for the BI component and K163587 for the incubator.

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 3-3** below. Simulated use testing was done side-by-side with the predicate device and all other testing demonstrates the PCD meets the criteria of the FDA guidances for CI and BI as they pertain to PCD.

Table 3-3. Summary of Non-clinical Testing vs Predicate

Test	Acceptance Criteria	Conclusion
Simulated Use	• Performance of the BI in the PCD is equivalent to the performance of the BI in the AAMI reference pack in their respective sterilization processes • Performance of the chemical integrator in the PCD is equivalent to the performance of the chemical integrator in AAMI reference pack in their respective processes • PCD provides an equivalent or greater challenge than the AAMI standardized test pack	PASS PASS PASS
BI in pack vs BI outside of pack	PCD provides a greater challenge to the process than the BI itself.	PASS
CI in pack vs CI outside of pack	PCD provides a greater challenge to the process than the integrator by itself.	PASS
Chemical Integrator	Chemical integrator does not reach endpoint before BI is inactivated.	PASS

"PASS" indicates that acceptance criteria were met and that the proposed pack performed at least as effectively as the predicate device.

7. Conclusion

The VERIFY Assert STEAM Process Challenge Device for Gravity Cycles 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 at least as safely and effectively as the legally marketed predicate device, Class II (21 CFR 880.2800, Product code FRC).