DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 24, 2017

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

Re: K162701
Trade/Device Name: VERIFY Assert Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2805
Regulation Name: Recombinant Biological Indicator
Regulatory Class: Class II
Product Code: OWP
Dated: February 17, 2017
Received: February 21, 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)*
K162701

Device Name
VERIFY Assert Self-Contained Biological Indicator

Indications for Use *(Describe)*
The VERIFY Assert Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing and product testing of the following steam sterilization processes.

Cycle Type	Temperature	Time
Dynamic Air Removal	270°F (132°C)	4 minutes
Dynamic Air Removal	275°F (135°C)	3 minutes
Gravity	250°F (121°C)	30 minutes
Gravity	270°F (132°C)	15 minutes

When used in conjunction with the Reader for the VERIFY Assert Self-Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator 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 K162701
VERIFY Assert Self-Contained Biological Indicator

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: Tony Piotrkowski
Senior Manager, Regulatory Affairs

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

Submission Date: March 15, 2017

Premarket Notification Number: K162701

1. Device Name

Trade Name: VERIFY Assert Self-Contained Biological Indicator

Common/usual Name: Biological Indicator (BI, SCBI)

Device Classification: Class II

Classification Name: Recombinant Biological Indicator
(21 CFR 880.2805, OWP)

2. Predicate Device

VERIFY CRONOS Self-Contained Biological Indicator K102469/DEN110006

Reference Devices

3M Attest Super Rapid Readout Biological Indicator, Model 1492 K121484
Attest Rapid Readout Biological Indicator, Model 1292 K090569
Attest Rapid Readout Biological Indicator, Model 1291 K926364

3. Description of Device

The product is intended to monitor the critical parameters of steam sterilization cycles described in the indications for use by producing an optical change (signal) that is detected by the STERIS proprietary reader, Incubator for VERIFY Assert Self-Contained Biolgoical Indicator in 40 minutes to confirm the viability of the biological indicator at the end of a steam sterilization process. The product consists of a biological organism known to be resistant to steam (*Geobacillus stearothermophilus*) and a defined nutrient media. 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 Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing and product testing of the following steam sterilization processes.

Cycle Type	Temperature	Time
Dynamic Air Removal	270°F (132°C)	4 minutes
Dynamic Air Removal	275°F (135°C)	3 minutes
Gravity	250°F (121°C)	30 minutes
Gravity	270°F (132°C)	15 minutes

When used in conjunction with the Reader for the VERIFY Assert Self-Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.

5. Summary of Technical Characteristics

A comparison of technical characteristics are summarized in **Table 5-1**.

Table 5-1 Summary of SCBI Physical Description and Technological Properties

Feature	Assert SCBI (proposed -K162701)	VERIFY Cronos SCBI (predicate-K102469)	Comparison
Intended Use	The VERIFY Assert Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing and product testing of the following steam sterilization processes: 270F, 4-minute dynamic air removal; 275F, 3-minnute dynamic air removal; 250 F, 30 minute gravity; 270, 15-minutes gravity. When used in conjunction with the Reader for the VERIFY Assert Self-Contained Incubator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.	For use by health care providers for qualification and routine monitoring of steam sterilization processes. The VERIFY Cronos SCBI is only validated to be used in the following steam sterilization cycles: 132 C vcuum-assitsted steam with 4-minute sterilization time; 135 C vcuum-assitsted steam with 3-minute sterilization time; 121 C gravity steam with 30-minute sterilization time; 132 C gravity steam with 15-minute sterilization time; 135 C gravity steam with 10-minute sterilization time; 132 C Steam Flush Pressure Pulse with 4- minute sterilization time.	Both are intended for monitoring steam sterilization cycles. Use statement for the proposed device has been aligned with AAMI ST79, Table 6 recommendations for use of BI. The Assert SCBI is claiming different cycles compared to the predicate (no 10-minute 135 gravity adding 135 SFPP). Simulated use testing in sterilizers with a load under pass and fail conditions demonstrate performance of the Assert SCBI in these additional cycles.
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Same
Mechanism of action	An enzyme, which is produced by the indicator organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety	An enzyme, which is produced by the plasmid, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety	Same mechanism of action, testing provided demonstrates conformance with ISO 11138 and the FDA guidance on BI submissions
Accessories	Automated incubator / reader	Automated incubator / reader	RIT testing performed with the proposed incubator/reader.
Viable spore population	1.0 - 4.0 x 10^6 spore/SCBI	1.0 - 5.0 x 10^6 spore/SCBI	Proposed population range within that of the predicate and both meet FDA guidance and ISO 11138 requirements

Feature	Assert SCBI (proposed -K162701)	VERIFY Cronos SCBI (predicate-K102469)	Comparison
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	121°C – 1.5 to 3.0 min 132°C – 10 to 30 sec 134°C – 8 sec to 20 sec 135°C – 8 sec to 20 sec	Both proposed and predicate meet criteria of ISO 11138-3 and FDA guidance
Culture Conditions	55- 59 °C, media included in SCBI, 40 minute incubation time.	55- 59 °C, media included in SCBI, 120 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.
Process indicator	STERIS STEAM Π (K112256)	STERIS STEAM Π (K112256)	Same indicator on both products

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
Reduced Incubation Time (RIT) Testing	Meets FDA's requirement of > 97% alignment of the 40-minute results with the conventional incubation time of 7 days	PASS
Viable spore population	1.0 – 4.0 x 10^6 spore/SCBI	1.6 – 1.9 x 10^6 spore/SCBI
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{121} \geq 2.29$ min $D_{132} \geq 49$ s $D_{135} \geq 40$ s
Survival Time	Meets the longer of FDA and ISO 11138-3 requirements	121 C $\geq$ 9.81 min 132 C $\geq$ 3.51 min 135 C $\geq$ 2.83 min
Kill Time	Meets the shorter of FDA and ISO 11138-3 requirements	121 C $\leq$ 25.57 min 132 C $\leq$ 9.21 min 135 C $\leq$ 7.73 min
Carrier growth inhibition / media growth promotion	Positive growth of less than 100 spores after primary packaging and media are subject to worst case steam exposure	PASS
Hold Time	Performance not affected if incubated within 72 hours of exposure to steam sterilization	PASS
Simulated Use	Demonstrate growth when exposed to abbreviated cycle and all kill in a full cycle	Abbreviated cycle – growth Full cycle – no growth

Test	Acceptance Criteria	Conclusion
Process indicator	Meets requirements for a "Class 1" process indicator of ISO 11140-1:2005	PASS Testing provided in K112256

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 substantially equivalent and is as safe and as effective as the legally marketed predicate device Class II (21 CFR 880.2805, Product code OWP).