May 22, 2020

STERIS Corporation
Anthony Piotrkowski
Regulatory Affairs Director
5960 Heisley Road
Mentor, Ohio 44060

Re: K200126
Trade/Device Name: VERIFY Assert Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: April 23, 2020
Received: April 24, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Elizabeth Claverie, M.S.
Assistant 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)*

K200126

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, load monitoring 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
VERIFY Assert Self-Contained Biological Indicator

Sponsor Facility

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1. Device Name

Trade Name:	VERIFY Assert Self-Contained Biological Indicator
Common/usual Name:	Biological Indicator (BI, SCBI)
Device Classification:	Class II
Classification Name:	Biological Sterilization Process Indicator (21 CFR 880.2800, FRC)

2. Predicate Device

Celerity 20 Steam Biological Indicator, K173634, as modified under K181686. (21 CFR 880.2800, FRC)

3. Reference Device

VERIFY Assert Self-Contained Biological Indicator, K162701, as modified under K181422. (21 CFR 880.2805, OWP)

4. 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, VERIFY Incubator for Assert Self-Contained Biological 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.

5. Intended Use/ Indications for Use

The VERIFY Assert Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing, load monitoring 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 VERIFY Incubator for Assert Self-Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.

6. Summary of Technical Characteristics

Table 5-1.Comparison of SCBI Physical Description and Technological Properties to Reference

Feature	VERIFY Assert SCBI (modified)	VERIFY Assert SCBI Reference (K162701)	Comparison
Intended Use	The VERIFY Assert Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization processes: 270F, 4-minute dynamic air removal; 275F, 3-minute dynamic air removal; 250 F, 30-minute gravity; 270, 15-minutes gravity. When used in conjunction with the VERIFY Incubator for Assert Self-Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.	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-minute dynamic air removal; 250 F, 30-minute gravity; 270, 15-minutes gravity. When used in conjunction with the VERIFY Incubator for Assert Self-Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.	Added load monitoring to the indications for use
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Identical
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 indicator organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.	Identical
Accessories	Automated incubator / reader	Automated incubator / reader	Identical
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	1.0 – 4.0 x 10^6 spore/BI	Identical
Resistance characteristics	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	Identical
Culture Conditions	55- 59 °C, media included in SCBI, 40-minute incubation time.	55- 59 °C, media included in SCBI, 40-minute incubation time.	Identical

Feature	VERIFY Assert SCBI (modified)	VERIFY Assert SCBI Predicate (K162701)	Comparison
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, cap with recovery media.	Identical
Process indicator	STERIS STEAM Π (K112256)	STERIS STEAM Π (K112256)	Identical
Label	Single-ply on cap edge	Two-ply on top of cap	This modification was cleared under K181442
Shelf-life	13 months	13 months	Identical
Exogenous DNA	None	plasmid pSTERIS-Q1	Plasmid has been removed

Table 5-2. Comparison of SCBI Physical Description and Technological Properties to Predicate Device

Feature	VERIFY Assert SCBI (modified)	Celerity 20 Steam SCBI Predicate (K173634)	Comparison
Intended Use	The VERIFY Assert Self-Contained Biological Indicator (SCBI) is for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization processes: • 270F, 4-minute dynamic air removal; • 275F, 3- minute dynamic air removal; • 250 F, 30-minute gravity; • 270, 15- minutes gravity. When used in conjunction with the VERIFY Incubator for Assert Self- Contained Biological Indicator, the VERIFY Assert Self-Contained Indicator provides a fluorescent result within 40 minutes.	The Celerity 20 Steam Biological Indicator is used for routine monitoring, qualification testing, load monitoring and product testing of the following steam sterilization cycles: • 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 Celerity™ Steam Incubator, the Incubator provides a fluorescent result within 20 minutes.	Predicate includes an indication for load monitoring The only differences are product name, read time and incubator
Indicator organism	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	*> 90% similarity to ATCC 7953 Geobacillus stearothermophilus*	Identical
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 indicator organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety	Identical
Accessories	Automated incubator / reader	Automated incubator / reader	Identical
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	1.0 - 4.0 x 10^6 spore/SCBI	Identical
Resistance	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq$ 8 s	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{135} \geq 8$ s	Identical

Feature	VERIFY Assert SCBI (modified)	Celerity 20 Steam SCBI Predicate (K173634)	Comparison
Culture Conditions	55- 59 °C, media included in SCBI, 40-minute incubation time.	55- 59 °C, media included in SCBI, 20-minute incubation time.	Reference device has a shorter read time
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, cap with recovery media.	Identical
Process indicator	STERIS STEAM Π (K112256)	STERIS STEAM Π (K112256)	Identical
Label	Single-ply on cap edge	Two-ply on top of cap	This modification was cleared under K181442
Shelf-life	13 months	13 months	Identical
Exogenous DNA	None	None	Identical

The modifications that have triggered this premarket notification include a change to remove the GMO component (plasmid pSTERIS-Q1) from the biological indicator spore and to revise the indications for use to include load monitoring.

7. 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	Purpose of the Test	Acceptance Criteria	Conclusion
Reduced Incubation Time (RIT) Testing	Validate the labeled incubation time of the SCBI	Meets FDA's requirement of > 97% alignment of the 40-minute results with the conventional incubation time of 7 days*, ♦	PASS
Viable spore population	Enumerate the number of viable spores per SCBI	$1.0 – 4.0 \times 10^6$ spore/SCBI**, ♦	$2.7 – 3.7 \times 10^6$ spore/SCBI
Resistance	Determine the resistance of the SCBI to steam	$D_{121} \geq 1.5$ min * $D_{132} \geq 10$ s * $D_{135} \geq 8$ s *	$D_{121} \geq 2.13$ min $D_{132} \geq 42$ s $D_{135} \geq 31$ s
Signal Generation	Validate that the SCBI will produce signal in its reader	All unexposed SCBI show positive growth signal in reader within 40 minutes of incubation♦	PASS
Hold Time	Demonstrate that performance of the SCBI is not affected by delaying incubation up to 72 hours	Performance not affected if incubated within 72 hours of exposure to steam sterilization♦	PASS

Test	Purpose of the Test	Acceptance Criteria	Conclusion
Simulated Use	Demonstrate SCBI performance in a steam sterilizer with the AAMI reference load (16 towel pack)	Demonstrate growth when exposed to abbreviated cycle and all kill in a full cycle♦	Abbreviated cycle – growth Full cycle – no growth

**Acceptance criteria based on recommendations in FDA Guidance Biological Indicator (BI) Premarket Notification [510(k)] Submissions*

***Minimum acceptance criteria based on recommendations in FDA Guidance Biological Indicator (BI) Premarket Notification [510(k)] Submissions*

♦*Acceptance criteria based on specifications of the reference device, VERIFY Assert Self-Contained BI*

8. Conclusion

The VERIFY Assert Self-Contained Biological Indicator has met the established performance criteria. The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device, K173634 Class II (21 CFR 880.2800, Product code FRC).