



June 13, 2018

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

Re: K181442

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: May 30, 2018
Received: June 1, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -
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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

Indications for Use

510(k) Number (if known)

K181442

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 K181442
VERIFY Assert Self-Contained Biological Indicator**

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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 with Recombinant-DNA Plasmid (21 CFR 880.2805, OWP)

2. **Predicate Device**

VERIFY Assert Self-Contained Biological Indicator, K162701

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, 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.

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.

<u>Cycle Type</u>	<u>Temperature</u>	<u>Time</u>
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.

5. Summary of Technical Characteristics

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

Feature	VERIFY Assert SCBI K181442	VERIFY Assert SCBI Predicate (K162701)	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-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.	Identical
Indicator organism	> 90% similarity to ATCC 7953 <i>Geobacillus stearothermophilus</i>	> 90% similarity to ATCC 7953 <i>Geobacillus stearothermophilus</i>	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 ≥ 1.5 min D ₁₃₂ ≥ 10 s D ₁₃₅ ≥ 8 s	D ₁₂₁ ≥ 1.5 min D ₁₃₂ ≥ 10 s D ₁₃₅ ≥ 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
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 II (K112256)	STERIS STEAM II (K112256)	Identical

Feature	VERIFY Assert SCBI K181442	VERIFY Assert SCBI Predicate (K162701)	Comparison
Label	Single-ply on cap edge	Two-ply on top of cap	Same adhesive and substrate, different format and location
Shelf-life	13 months	13 months	Identical

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	Result
Simulated Use	BI is inactivated when exposed in a worst-case cycle with a worst-case load	No growth of BI

7. Conclusion

The VERIFY Assert Self-Contained Biological Indicator has met the established performance criteria. The conclusions drawn from the nonclinical tests performed demonstrate the subject device is as safe, as effective, and performs as well or better than the legally marketed predicate device, K162701 Class II (21 CFR 880.2805, Product code OWP).