January 3, 2019

STERIS Corporations
Gregory Land
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K183300
Trade/Device Name: VERIFY V24 Self-Contained Biological Indicator, VERIFY V24 Biological Indicator Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 26, 2018
Received: November 27, 2018

Dear Gregory Land:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183300

Device Name
VERIFY V24 Biological Indicator Challenge Pack

Indications for Use *(Describe)*
The VERIFY V24 BI Challenge Pack is intended for qualification testing of the V PRO 1, V-PRO 1 Plus, VPRO maX, V-PRO maX 2, V-PRO 60 and V PRO s 2 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.

The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the Sterilizers.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K183300

Device Name
VERIFY V24 Self-Contained Biological Indicator

Indications for Use *(Describe)*
The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizer cycles:
• Lumen, Non Lumen, Flexible, Fast and Fast Non Lumen Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s 2 Sterilizers
• STERRAD® 100S Sterilizer (default cycle)
• STERRAD® 200 Sterilizer (default cycle)
• Standard and Advanced Cycles of the STERRAD® NX Sterilizer to include sterilizers with All Clear Technology
• Express, Flex Scope and Standard Cycles of the STERRAD® 100NX Sterilizer to include sterilizers with All Clear technology

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)

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510(k) Summary
For
VERIFY® V24 Self-Contained Biological Indicator
And
VERIFY® V24 Self-Contained Biological Indicator Challenge Pack

Sponsor Facility

STERIS Corporation
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Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Manufacturing Facility

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Phone: (440) 392-7800
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Contact: Gregory Land
Senior Regulatory Affairs Specialist

Telephone: (440) 392-7424
Fax No: (440) 357-9198
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Submission Date: Janary 2, 2019

Premarket Notification Number: K183300

1. Device Name – Self-Contained Biological Indicator(SCBI)

Trade Name:	VERIFY® V24 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 – Self-Contained Biological Indicator(SCBI)

VERIFY® V24 Self-Contained Biological Indicator, K172748

3. Description of Device – Self-Contained Biological Indicator(SCBI)

The VERIFY V24 Self-Contained Biological Indicator (SCBI) is used by healthcare facilites to monitor the V-PRO® Low Temperature Sterilization Systems. It is designed to accompany medical devices placed in the sterilizer.

The user places the VERIFY V24 SCBI into the V-PRO Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the SCBI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The SCBI is activated by sealing the vial and rupturing the medium ampoule using the STERIS VERIFY SCBI HP activator. The activator automatically seals the SCBI vial and releases the growth media.

The activated SCBI is incubated at 55-60°C for ≥ 24 hours. The SCBI indicates a pass if the media remains orange and non-turbid. The SCBI indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

4. Intended Use/ Indications for Use – Self-Contained Biological Indicator(SCBI)

The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles:

- Non Lumen, Flexible, Lumen, Fast and Fast Non Lumen Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s 2 Sterilizers
- Standard Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without All Clear Technology.
- Express, Flex Scope and Standard Cycles of the STERRAD® 100 NX Sterilizer to include sterilizers with or without All Clear Technology

5. Summary of Technical Characteristics – Self-Contained Biological Indicator(SCBI)

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

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

Feature	VERIFY V24 SCBI (proposed)	VERIFY V24 SCBI Predicate (K172748)	Comparison
Intended Use	The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles: • Non Lumen, Flexible, Lumen, Fast and Fast Non Lumen Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s 2 Sterilizers • Standard Cycle of the STERRAD® 100S Sterilizer • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear Technology • Express, Flex Scope and Standard Cycles of the STERRAD® 100 NX Sterilizer to	The VERIFY V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizers and cycles: • Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers • Standard Cycle of the STERRAD 100S Sterilizer • Standard and Advanced Cycles of the STERRAD NX Sterilizer • Express, Flex Scope and Standard Cycles of the STERRAD 100 NX Sterilizer	The proposed and predicate devices are identical. The Fast Cycle is a new cycle in the V-PRO s2 Low Temperature Sterilizer, which has been submitted in this premarket notification. The addition of use in STERRAD cycles with All Clear has been added

Feature	VERIFY V24 SCBI (proposed)	VERIFY V24 SCBI Predicate (K172748)	Comparison
	include sterilizers with or without All Clear Technology		
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same
Mechanism of action	Visual detection of growth based on media color change in the presence of surviving indicator organisms.	Visual detection of growth based on media color change in the presence of surviving indicator organisms.	Same. simulated use testing demonstrate appropriate monitoring of indicated sterilization cycles.
Accessories	VERIFY Incubator and VERIFY SCBI HP Activator (optional)	VERIFY Incubator and VERIFY SCBI HP Activator (optional)	Same
Viable spore population	2.0 – 3.4 x 10^6 spore/BI	2.0 – 3.4 x 10^6 spore/BI	Same. Both contain greater than 10^6 spores/BI.
Resistance characteristics	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 @ 2.7 mg/L H_2O_2: • D-value 4.0 – 8.0 sec • Survival Time 4 - 30 sec • Kill Time ≤ 16 min	Same. Simulated use testing verifies suitability for use in claimed cycles.
Culture Conditions	55- 60°C, media included in SCBI, 24 hour incubation time.	55- 60°C, media included in SCBI, 24 hour incubation time.	Same
Primary Packaging	Direct inoculum on plastic vial, glass ampoule with recovery media.	Direct inoculum on plastic vial, glass ampoule with recovery media.	Same
Process indicator	VERIFY V24 Self-Contained Biological Indicator Vail Label (subject of a separate submission); magenta to orange/yellow color change.	VERIFY V-PRO Chemical Indicator magenta to yellow color change.	Same
Shelf-life	6 months: An 18-month shelf life is established for the SCBI however the throughput process indicator (subject to a separate submission) has a shelf life of 6 months so the maximum labeled shelf life for the SCBI is 6 months	9 months: An 18-month shelf life is established for the SCBI however the throughput process indicator (K140515) has a shelf life of 9 months so the maximum labeled shelf life for the SCBI is 9 months	Same

6. Summary of Nonclinical Tests – Self-Contained Biological Indicator(SCBI)

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
½ & ¾ Cycle Performance	All test SCBIs exposed in either the ½ or ¾ cycle display passing results	PASS
Simulated Use	• All processed SCBIs exhibit negative growth results • All processed SCBI Label PIs exhibit a "pass" result • All processed CIs exhibit a "pass" result	PASS
Verification of Viable Spore Population after exposure to ALLClear	• The mean population of V24 SCBI exposed to the ALLClear pre-conditioning was -50% to +300% of the unexposed V24 SCBI population	PASS

Table 5-4. Summary of Testing Previously Submitted for VERIFY V24 SCBI (K140499)

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	$2.0 – 3.4 \times 10^6$ spore/SCBI	PASS
D-value	4-8 sec	PASS
Survival Time	4-30 sec	PASS
Kill Time	≤ 16 min	PASS
Hold Time	Performance not affected if incubated within 72 hours of exposure to VHP sterilization	PASS

7. Device Name – Challenge Pack

Trade Name: VERIFY® V24 Self-Contained Biological Indicator Challenge Pack

Common/usual Name: Biological Indicator (BI) Process Challenge Device

Device Classification: Class II

Classification Name: Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

8. Predicate Device – Challenge Pack

VERIFY® V24 Self-Contained Biological Indicator, K172748

9. Description of Device – Challenge Pack

The VERIFY V24 Biological Indicator Challenge Pack is used by healthcare facilities for qualification testing of the V-PRO Low Temperature Sterilization Systems following installation, relocations, malfunctions or major repairs. The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital defined challenge load is not included.

The user places the VERIFY V24 Biological Indicator Challenge Pack into the V-PRO Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the VERIFY HPU Chemical Indicator (CI) and the VERIFY V24 Self-Contained Biological Indicator (SCBI) contained in the challenge pack are retrieved. The CI is assessed for a passing color change immediately and the SCBI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The SCBI is activated by sealing the vial and rupturing the medium ampoule using the STERIS VERIFY SCBI HP activator. The activator automatically seals the SCBI vial and releases the growth media.

The activated SCBI is incubated at 55-60°C for ≥ 24 hours. The SCBI indicates a pass if the media remains orange and non-turbid. The SCBI indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

10. Intended Use/ Indications for Use – Challenge Pack

The VERIFY V24 BI Challenge Pack is intended for qualification testing of the V-PRO 1, V-PRO 1 Plus, VPRO maX, V-PRO maX 2, V-PRO 60 and V-PRO s 2 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.

The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the Sterilizers.

11. Summary of Technical Characteristics – Challenge Pack

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

Table 5-1. Challenge Pack Physical Description and Technological Properties vs the Predicate Device

Feature	VERIFY V24 Biological Indicator Challenge Pack (proposed)	VERIFY V24 Biological Indicator Challenge Pack Predicate (K172748)	Comparison
Intended Use	The VERIFY V24 Challenge Pack is intended for qualification testing of V-PRO® 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2, V-PRO 60 and V-PRO s 2 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs. The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in Sterilizer qualification testing.	The VERIFY V24 Challenge Pack is intended for qualification testing of V-PRO® 1, V PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs. The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is **not** intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in Sterilizer qualification testing.	The proposed and predicate devices are identical. The V-PRO s 2 Low Temperature Sterilizer, is a new model Sterilizer which has been submitted in a separate premarket notification (K182568).
Biological Indicator	VERIFY V24 Self-Contained Biological Indicator (subject of this submission)	VERIFY V24 Self-Contained Biological Indicator	Same
Class 1 Chemical Indicator	The CELERITY HP Chemical Indicator (subject of a separate Premarket Notification) is placed inside the pouch. A throughput process indicator is also located on the VERIFY V24 SCBI label.	The VERIFY HPU Chemical Indicator is placed inside the pouch. A throughput process indicator is also located on the VERIFY V24 SCBI label.	Same
Means to distinguish processed from unprocessed	Chemical indicator of proposed device visible through the pack.	Chemical indicator of proposed device visible through the pack.	Same

12. Summary of Nonclinical Tests – Challenge Pack

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
Comparitive Dose Response to Biological Model	The challenge pack shall demonstrate equal or greater resistance as compared to the worst case biological model	PASS
Simulated Use	• All processed SCBIs exhibit negative growth results • All processed SCBI Label PIs exhibit a "pass" result • All processed CIs exhibit a "pass" result	PASS

13. Conclusion

Based on the intended use, technological characteristics and nonclinical performance data, the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device, VERIFY V24 Self-Contained Biological Indicator (cleared in K172748), Class II (21 CFR 880.2800) product code FRC.

Based on the intended use, technological characteristics and nonclinical performance data, the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device, VERIFY V24 Biological Indicator Challenge Pack (cleared in K172748), Class II (21 CFR 880.2800), product code FRC.