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STERIS®



**510(k) Summary
for
VERIFY® V24 Self-Contained Biological Indicator**

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Submission Date: July 10, 2014

1. Device Name

Trade Name: VERIFY® V24 Self-Contained Biological Indicator
Common/usual Name: Biological Indicator (BI)
Device Class: Class II
Classification Name: Indicator, Biological Sterilization Process
(21 CFR 880.2800, FRC)

2. Predicate Device

Verify Self-Contained Biological Indicator (SCBI) for Vaporized VH2O2
Sterilization Processes (K073244) modified under K090514.

3. Description of Device

The VERIFY V24 Self-Contained Biological Indicator (SCBI) is used by healthcare providers 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 Self-Contained Biological Indicator 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

The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the Lumen, Non Lumen and Flexible cycles of V-PRO® Low Temperature Sterilization Systems.

5. **Description of Safety and Substantial Equivalence**

The VERIFY V24 Self-Contained Biological Indicator has the identical characteristics as compared to its predicate device, the Verify Self-Contained Biological Indicator (SCBI) for Vaporized **VH2O2** Sterilization Processes (name changed in K090514). A comparison table that outlines the characteristics of the proposed and predicate devices is below.

Feature	Proposed Device VERIFY V24 Self- Contained Biological Indicator	Predicate Device Verify Self-Contained Biological Indicator (SCBI) for Vaporized VH2O2 Sterilization Processes (K073244) modified under K090514	Comparison
Intended Use: Method of Monitoring Sterilization Process Parameters	The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the Lumen, Non Lumen and Flexible cycles of V-PRO® Low Temperature Sterilization Systems.	A standard method for frequent monitoring of the V-PRO 1 Low Temperature Sterilizer cycle	The device has been previously cleared for use with the V-PRO 1 (K073244), V-PRO 1 Plus (K083097) and V-PRO maX (K102330) Low Temperature Sterilization Systems. The proposed device is intended to add the new V-PRO 60 unit to the claims and is the focus of performance testing in this submission.
Labeling	<ul style="list-style-type: none"> • Vial Label • Certificate of Performance • Carton Label • Instructions for Use 	<ul style="list-style-type: none"> • Vial Label • Certificate of Performance • Carton Label • Instructions for Use 	Proposed and predicate devices have identical labeling.
Organism: Species & Strain	<i>Geobacillus stearothermophilus</i> ATCC 7953 spores	<i>Geobacillus stearothermophilus</i> ATCC 7953 spores	Proposed and predicate devices utilize the identical organism species and strain
Accessories	<ul style="list-style-type: none"> • VERIFY Incubator (Optional) • VERIFY Activator (Optional) • Throughput Process Indicator 	<ul style="list-style-type: none"> • VERIFY Incubator (Optional) • VERIFY Activator (Optional) • Throughput Process Indicator 	Proposed and predicate devices utilize the identical accessories
Viable Spore Population	> 10 ⁶ CFU	> 10 ⁶ CFU	Proposed and predicate devices specify the same viable spore population

**K140499/S001 STERIS Response to 4/28/14 Request for Additional Information
 VERIFY® V24 Self-Contained Biological Indicator and VERIFY® V24 Biological Indicator
 Challenge Pack**

Feature	Proposed Device VERIFY V24 Self- Contained Biological Indicator	Predicate Device Verify Self-Contained Biological Indicator (SCBI) for Vaporized VH2O2 Sterilization Processes (K073244) modified under K090514	Comparison
Resistance characteristics @ 2.7 mg/L H ₂ O ₂ :	<ul style="list-style-type: none"> • D-value • Survival/Kill Window 	<ul style="list-style-type: none"> • D-value • Survival/Kill Window 	Proposed and predicate devices have the same resistance characteristics specifications
Culture Conditions	<ul style="list-style-type: none"> • Trypticase Soy Broth Based Media • Incubation Temp: 55-60°C • Incubation Time: ≥24 hours 	<ul style="list-style-type: none"> • Trypticase Soy Broth Based Media • Incubation Temp: 55-60°C • Incubation Time: ≥24 hours 	Proposed and predicate devices utilize identical culture conditions. Please note that the reduced incubation time of 24 hours was cleared under K090514.
Carrier Materials	Polypropylene Vial	Polypropylene Vial	Proposed and predicate devices have identical carrier materials
Packaging: <ul style="list-style-type: none"> • Primary Pack • Secondary Pack 	<ul style="list-style-type: none"> • Polypropylene Vial • 50 Indicators Supplied in a Cardboard Box 	<ul style="list-style-type: none"> • Polypropylene Vial • 50 Indicators Supplied in a Cardboard Box 	Primary and packaging materials are identical for predicate and proposed devices.
Storage Conditions	16 – 25°C, 30 - 60% RH	16 – 25°C, 30 - 60% RH	Proposed and predicate devices specify identical storage conditions.
Shelf-life	As indicated on labeling	As indicated on labeling	Proposed and predicate devices claim identical shelf life.

The proposed and predicate devices are therefore identical in respect to the labeling, organism, accessories, spore population, resistance characteristics, culture conditions, carrier materials, packaging, storage conditions and claimed shelf life. The only difference between the subject and predicate device is the claimed intended use. This submission therefore focuses on testing to qualify the proposed biological indicator for use in the V-PRO 60 Low Temperature Sterilization System to demonstrate substantial equivalence to the claimed predicate.

**K140499/S001 STERIS Response to 4/28/14 Request for Additional Information
VERIFY® V24 Self-Contained Biological Indicator and VERIFY® V24 Biological Indicator
Challenge Pack**

Summary of Nonclinical Tests:

Test	Result
SCBI Half Cycle Performance Evaluation in the V-PRO 60 Sterilizer	Pass SCBIs were sterile in half-cycle testing.
SCBI Growth Inhibition Following Exposure to V-PRO 60 Cycle	Pass There was no growth inhibition and no effect of the sterilization process on the media.
SCBI Simulated Use in the V-PRO 60 Sterilizer	Pass Simulated use performance has been successfully demonstrated.
SCBI Worst Case Location in the V-PRO 60 Sterilizer	Pass Worst case location for SCBI placement was determined.

All performance studies for the VERIFY V24 Self-Contained Biological Indicator recommended within FDA Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions have been previously completed, submitted and cleared under K073244 and K090514. These studies and the results are summarized in the appropriate sections throughout this submission and include, but are not limited to:

- Viable Spore Population Assay
- Resistance Characteristics
- Carrier and Primary Packaging Evaluation
- Holding Time Assessment
- Recovery Methods
- Shelf Life

Therefore, the VERIFY V24 Self-Contained Biological Indicator is substantially equivalent to the claimed predicate device since it is identical in design and performance characteristics and has, in addition, been qualified for use in the V-PRO 60 Sterilizer.



**510(k) Summary
for
VERIFY® V24 Biological Indicator Challenge Pack**

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Telephone: (440) 392-7690
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Summary Date: July 10, 2014

6. Device Name

Trade Name: VERIFY® V24 Biological Indicator Challenge Pack
Common/usual Name: Biological Indicator (BI) Process Challenge Device
Device Class: Class II
Classification Name: Indicator, Biological Sterilization Process
(21 CFR 880.2800, FRC)

7. Predicate Device

Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes, K103331.

8. Description of Device

The VERIFY V24 Biological Indicator Challenge Pack is used by healthcare providers for qualification testing of the V-PRO 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 user places the VERIFY V24 Biological Indicator Challenge Pack into the V-PRO Sterilizer 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 media 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 if the media changes from orange to yellow and/or if the media is turbid.

9. Intended Use

The VERIFY V24 Biological Indicator Challenge Pack is intended for qualification testing of the Lumen, Non Lumen and Flexible Cycles in V-PRO 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.

10. Description of Safety and Substantial Equivalence

The VERIFY V24 Biological Indicator Challenge Pack has the identical characteristics as compared to its predicate device, the Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes, K103331. A comparison table that outlines the characteristics of the proposed and predicate devices is below.

Feature	Proposed Device VERIFY V24 Biological Indicator Challenge Pack	Predicate Device Verify® Biological Indicator Challenge Pack for Vaporized <u>VH2O2</u> Sterilization Processes, K103331	Comparison
Intended Use	<p>The VERIFY V24 Biological Indicator Challenge Pack is intended for qualification testing of the Lumen, Non Lumen and Flexible Cycles in V-PRO Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.</p> <p>The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.</p> <p>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.</p>	<p>The Verify Biological Indicator Challenge Pack for Vaporized <u>VH2O2</u> Sterilization Processes is intended for qualification testing of the Amsco® V-PRO™ 1, the Amsco V-PRO 1 Plus (Lumen and Non Lumen Cycles, K092906) and the V-PRO™ maX (Flexible, Lumen and Non Lumen Cycles) Low Temperature Sterilization Systems following installation, relocation, malfunctions or major repairs.</p> <p>The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.</p> <p>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 V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers.</p>	<p>The device has been previously cleared for use with the V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems (K103330). This submission is intended to add the new V-PRO 60 Sterilizer to the claimed intended uses of the device and is the focus of performance testing in this submission.</p>

**K140499/S001 STERIS Response to 4/28/14 Request for Additional Information
 VERIFY® V24 Self-Contained Biological Indicator and VERIFY® V24 Biological Indicator
 Challenge Pack**

Feature	Proposed Device VERIFY V24 Biological Indicator Challenge Pack	Predicate Device Verify® Biological Indicator Challenge Pack for Vaporized <u>VH2O2</u> Sterilization Processes, K103331	Comparison
Biological Indicator (BI)	VERIFY V24 SCBI (subject of this submission)	Verify V24 SCBI (K090514)	The biological indicator is identical in materials.
Mechanism to Increase the Resistance of the BI	The VERIFY V24 SCBI is packaged with a sheet of polyurethane foam which serves as a physical barrier to penetration as well as a reservoir for hydrogen peroxide.	The Verify V24 SCBI is packaged with a sheet of polyurethane foam which serves as a physical barrier to penetration as well as a reservoir for hydrogen peroxide.	The mechanism to increase BI resistance is identical in the proposed and predicate devices
BI Secondary Packaging	The SCBI and foam sheet are placed within a Tyvek pouch.	The SCBI and foam sheet are placed within a Tyvek pouch.	The BI Secondary Packaging is identical in the proposed and predicate devices.
Class 1 Chemical Indicator	The VERIFY HPU Chemical Indicator (separate Premarket Notification submission) is placed in the pouch. A throughput process indicator is also located on the VERIFY V24 SCBI label.	The Verify V-PRO Chemical Indicator (K091174) is placed in the pouch. A throughput process indicator is also located on the Verify V24 SCBI label.	The Class 1 Chemical Indicator intended to be used in the proposed device is similar to that in the predicate device. A separate, concurrent Premarket Notification is being submitted for the Class 1 Process Indicator
Resistance Characteristics	The VERIFY V24 Biological Indicator Challenge Pack is more resistant to the V-PRO 60 Sterilizer cycles than is the biological model developed for validation of those sterilization cycles.	The Verify Biological Indicator Challenge Pack for Vaporized <u>VH2O2</u> Sterilization Processes is more resistant to the V-PRO maX Sterilizer cycles than is the biological model developed for validation of those sterilization cycles.	Performance testing provided in this submission demonstrates that the VERIFY V24 Biological Indicator Challenge Pack is more resistant to the V-PRO 60 Sterilizer cycles than is the biological model developed for validation of those sterilization cycles.

The proposed and predicate devices are therefore identical except for the claimed intended use and the Class 1 Chemical Indicator, which has been submitted under a separate concurrent Premarket Notification. This submission therefore focuses on testing to qualify the proposed device for use in the V-PRO 60 Low Temperature Sterilization System to demonstrate substantial equivalence to the claimed predicate.

Summary of Nonclinical Tests:

Test	Result
Resistance Characterization	Pass Challenge Pack resistance is equivalent or greater than the biological models used to validate the V-PRO 60 Low Temperature Sterilization System.
Simulated Use Evaluation	Pass The VERIFY HPU Chemical Indicator and VERIFY V24 SCBI yielded passing results when evaluated under worst case simulated use conditions.
Worst Case Location	Pass The worst case location within the V-PRO 60 Sterilizer Chamber was identified

The subject device is similar to the claimed predicate and conforms with all performance studies recommended within FDA Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions.

Therefore, the VERIFY V24 Biological Indicator Challenge Pack is substantially equivalent to the claimed predicate device for use in the V-PRO 60 Sterilizer.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 17, 2014

Steris Corporation
Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
5960 Heisley Road
Mentor, OH 44060

Re: K140499

Trade/Device Name: Verify® V24 Self-Contained Biological Indicator, Verify® V24
Biological Indicator Challenge Pack

Regulation Number: 21 CFR 880.2800

Regulation Name: FRC

Regulatory Class: II

Product Code: FRC

Dated: June 19, 2014

Received: June 24, 2014

Dear Mr. Brodbeck:

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 yours,


Tejasfiri Purohit-Sheth, M.D. Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)
K140499

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 Lumen, Non Lumen and Flexible cycles of V-PRO® Low Temperature Sterilization Systems.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie



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Indications for Use

510(k) Number (if known)
K140499

Device Name
VERIFY® V24 Biological Indicator Challenge Pack

Indications for Use (Describe)

The VERIFY V24 Biological Indicator Challenge Pack is intended for qualification testing of the Lumen, Non Lumen and Flexible Cycles in V-PRO 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie

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