STERIS®

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

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Submission Date: March 20, 2014

1. Device Name

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

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 and the STERRAD® 100S, STERRAD 200, STERRAD NX and STERRAD 100NX (Express, Standard and Flex Scope Cycles) Sterilizers. 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 or STERRAD Sterilizer 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 following sterilizer cycles:

- Lumen, Non Lumen and Flexible Cycles of the V-PRO® Low Temperature Sterilization Systems
- Default Cycle of the STERRAD 100S Sterilizer
- Default Cycle of the STERRAD 200 Sterilizer

- Standard and Advanced Cycles of the STERRAD NX Sterilizer
- Express, Standard and Flex Scope Cycles of the STERRAD 100NX Sterilizer

5. Description of Safety and Substantial Equivalence

The VERIFY V24 Self-Contained Biological Indicator has the identical accessories, viable population, resistance characteristics, culture conditions, primary and secondary packaging, and storage conditions as compared to its predicate device, the Verify Self-Contained Biological Indicator (SCBI) for Vaporized VH2O2 Sterilization Processes (name changed in K090514). Testing submitted (**Table 5-1**) focused on qualification of the subject device for its proposed new indications for use in STERRAD Sterilizers as all other characteristics remain identical to the predicate device.

Table 5-1. Summary of Nonclinical Tests:

Test	Result
SCBI Half Cycle Performance Evaluation in the STERRAD Sterilizer Cycles	Pass SCBIs were sterile in half-cycle testing.
SCBI Growth Inhibition Following Exposure to STERRAD Sterilizer Cycles	Pass There was no growth inhibition and no effect of the sterilization process on the media.
SCBI Simulated Use in the STERRAD Sterilizer Cycles	Pass Simulated use performance has been successfully demonstrated.

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

6. Technological Characteristics

Table 5-2 compares technological characteristics and specifications to the predicate device. The proposed biological indicator is identical in composition and has the same performance specifications as the predicate.

Table 5-2. VERIFY V24 Self-Contained Biological Indicator

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 following sterilizers and cycles: • Lumen, Non Lumen and Flexible Cycles of the V-PRO® Low Temperature Sterilization Systems • Default Cycle of the STERRAD 100S Sterilizer • Default Cycle of the STERRAD 200 Sterilizer •Standard and Advanced Cycles of the STERRAD NX Sterilizer • Express, Standard and Flex Scope Cycles of the STERRAD 100NX Sterilizer	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 listed ASP STERRAD Sterilization system cycles to the claims.
Labeling	• Vial Label • Certificate of Performance • Carton Label • Instructions for Use	• Vial Label • Certificate of Performance • Carton Label • Instructions for Use	Proposed and predicate devices have identical labeling except that the instructions for use of the proposed device include the listed STERRAD Sterilizer cycles.
Organism: Species & Strain	*Geobacillus stearothermophilus* ATCC 7953 spores	*Geobacillus stearothermophilus* ATCC 7953 spores	Same
Accessories	• VERIFY Incubator (Optional) • VERIFY Activator (Optional) • Throughput Process Indicator	• VERIFY Incubator (Optional) • VERIFY Activator (Optional) • Throughput Process Indicator	Same
Viable Spore Population	The specification range for viable spore population is identical for the proposed device and predicate.		

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	The specification range for D-value, survival time and kill time are identical for the proposed device and predicate.		
Culture Conditions	• V24 SCBI Growth Media • Incubation Temp: 55-60°C • Incubation Time: ≥24 hours	• V24 SCBI Growth Media • Incubation Temp: 55-60°C • Incubation Time: ≥24 hours	Same Please note that the reduced incubation time of 24 hours was cleared under K090514.
Carrier Materials	Polypropylene Vial	Polypropylene Vial	Same
Packaging: • Primary Pack • Secondary Pack	• Polypropylene Vial • 50 Indicators Supplied in a Cardboard Box	• Polypropylene Vial • 50 Indicators Supplied in a Cardboard Box	Same
Storage Conditions	16 – 25°C, 30 - 60% RH	16 – 25°C, 30 - 60% RH	Same
Shelf-life	The labeled shelf life is identical for the proposed device and predicate.		

7. Conclusion

The VERIFY V24 Self-Contained Biological Indicator is identical in composition and has the same performance specifications as the predicate, therefore, it is substantially equivalent to the claimed predicate device since it is identical in design and performance characteristics and has been qualified for routine monitoring of the STERRAD 100S default cycle, STERRAD 200 default cycle, STERRAD NX Standard and Advanced cycles and STERRAD 100NX Express, Standard and Flex Scope cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

June 16, 2014

STERIS Corporation
William Brodbeck, Ph.D
Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K140708
Trade/Device Name: VERIFY® V24 Self Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator, Biological Sterilization Process
Regulatory Class: II
Product Code: FRC
Dated: March 20, 2014
Received: March 21, 2014

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

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): K140708

Device Name: **VERIFY® V24 Self-Contained Biological Indicator**

Indications For Use:

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

- Lumen, Non Lumen and Flexible Cycles of the V-PRO® Low Temperature Sterilization Systems
- Default Cycle of the STERRAD 100S Sterilizer
- Default Cycle of the STERRAD 200 Sterilizer
- Standard and Advanced Cycles of the STERRAD NX Sterilizer
- Express, Standard and Flex Scope Cycles of the STERRAD 100NX Sterilizer

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
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