p184

SEP - 1 2011

STERIS®

510(k) Summary
For
Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Robert F. Sullivan.
Senior Director, FDA Regulatory Affairs
Telephone: (440) 392-7695
Fax No: (440) 357-9198

Summary Date: January 28, 2011

1. Device Name

Trade Name:	Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes
Common/usual Name:	Biological Indicator (BI) Process Challenge Device
Classification Name:	Indicator, Biological Sterilization Process (21 CFR 880.2800, FRC)

2. Predicate Device

Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes, K092906, December 30, 2009.

3. Description of Device

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes is used by healthcare providers for qualification testing of the Amsco® V-PRO™ 1 Low Temperature Sterilization System, the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen Cycles) and the V-PRO™ maX (Flexible, Lumen and Non Lumen Cycles) 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 Biological Indicator Challenge Pack into the Amsco V-PRO Sterilizer and performs a sterilization cycle. After cycle completion, the Verify V-PRO Chemical Indicator (CI) and the Verify V24 Self-Contained Biological Indicator (SCBI) contained in the challenge pack are retrieved. The CI is accessed 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.

4. Intended Use

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 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.

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 V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers.

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes is intended for qualification testing of the following cycles.

Sterilization Cycle	Sterilant/ Injection (g)	# Injections	Sterilant Exposure Time (min)
Amsco V-PRO 1 Cycle Amsco V-PRO 1 Plus Lumen Cycle Amsco V-PRO maX Lumen Cycle	2.1	4	32
Amsco V-PRO 1 Plus Non Lumen Cycle Amsco V-PRO maX Non Lumen Cycle	2.1	4	12
Amsco V-PRO maX Flexible Cycle	2.1	4	12

5. Description of Safety and Substantial Equivalence

No substantial changes were made to the Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes design, cleared in K092906, for qualification in the V-PRO maX Sterilizer Flexible Cycle. The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes does not raise any new issues of safety and effectiveness. The performance data obtained through nonclinical tests and outlined below demonstrates the Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes substantial equivalence to the predicate device.

Summary of Nonclinical Tests:

Test	Result
Resistance Characterization	**Pass** Challenge Pack resistance is equivalent or greater than the biological model used to validate the Lumen and Non Lumen Cycles of the V-PRO 1 Plus Low Temperature Sterilization System. Challenge Pack resistance is equivalent or greater than the biological model used to validate the Flexible Cycle of the V-PRO maX Low Temperature Sterilization System
Simulated Use Evaluation	**Pass** The Verify V-PRO CI and Verify V24 SCBI yielded passing results when evaluated under worst case simulated use conditions.
Process Indicator Performance Evaluation	**Pass** The Process Indicator in the Challenge Pack demonstrated a complete color change under "Pass" conditions and an incomplete color change under "Fail" conditions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Robert F. Sullivan
Senior Director, FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

SEP - 1 2011

Re: K103331
Trade/Device Name: Verify® Biological Indicator Challenge Pack for Vaporized VH202 Sterilization Processes
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: August 25, 2011
Received: August 26, 2011

Dear Mr. Sullivan:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes**

Indications For Use:

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes is intended for qualification testing of the Amsco® V-PRO™ 1 (cleared under K073618), Amsco V-PRO 1 Plus (Lumen and Non Lumen Cycles, K092906), and Amsco V-PRO maX (Lumen, Non Lumen and Flexible Cycles) 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 V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers.

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes is intended for qualification testing of the following cycles.

Sterilization Cycle	Sterilant/ Injection (g)	# Injections	Sterilant Exposure Time (min)
Amsco V-PRO 1 Cycle Amsco V-PRO 1 Plus Lumen Cycle Amsco V-PRO maX Lumen Cycle	2.1	4	32
Amsco V-PRO 1 Plus Non Lumen Cycle Amsco V-PRO maX Non Lumen Cycle	2.1	4	12
Amsco V-PRO maX Flexible Cycle	2.1	4	12

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103331