STERIS®

JAN - 7 2009

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

STERIS Corporation
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Summary Date: January 05, 2009
Submission: K073618

1. Device Name

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

2. Predicate Device

STERRAD® Sterilizer CycleSure® Test Pack, K051643, August 19, 2005.

3. Description of Device

The Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes is used by healthcare providers for periodic qualification testing of the Amsco® V-PRO™ 1 Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs. It is designed to be placed into an otherwise empty chamber.

The user places the Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes into the Amsco V-PRO 1 Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the Verify Vaporized VH2O2 Process Indicator (CI) and the Verify® Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes (SCBI) contained in the challenge pack are retrieved. The CI is accessed for a passing color change immediately. The results of the CI, a class 1 indicator, do not provide proof of Sterilizer qualification. 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. The SCBI indicates a pass if the media remains purple and non-turbid. The SCBI indicates a failure if the media changes from purple to yellow and/or if the media is turbid. The V-PRO 1

Sterilizer passes qualification testing when three Challenge Pack SCBIs, processed in separate sterilization cycles, signal sterile results.

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 Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs. The challenge pack is placed in an otherwise empty V-PRO 1 Sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is **not** intended for routine monitoring of the V-PRO 1 Sterilizer. It has been tested and validated solely for use in periodic testing of the V-PRO 1 Sterilizer.

5. Description of Safety and Substantial Equivalence

The Verify Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes has the same or similar intended use, type of BI, method to increase the resistance of the BI, packaging, and resistance characteristics as compared to its predicate device the STERRAD® Sterilizer CycleSure® Test Pack.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

John R. Scoville, Jr.
Fellow, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

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Re: K073618
Trade/Device Name: Verify® Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: December 17, 2008
Received: December 18, 2008

Dear Mr. Scoville:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Ginette Y. Michaud, M. D.
Division Acting 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): K073618

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

Indications For Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X___ (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: K073618