STERIS®

MAY 28 2008

510(k) Summary
For
Verify® Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes

STERIS Corporation
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Fellow
Regulatory Affairs
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Submission Date: May 16, 2008

1. Device Name

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

2. Predicate Device

STERRAD® Cyclesure™ Biological Indicator, K994055, Feb 13, 2002
STERRAD® Cyclesure Biological Indicator, K031226, May 2, 2003
STERRAD® Cyclesure Biological Indicator, K071014 May 24, 2007

3. Description of Device

The Verify Self-Contained Biological Indicator (SCBI) for Vaporized VH2O2 Sterilization Processes is used by healthcare providers to monitor the Amsco® V-PRO™ 1 Low Temperature Sterilizer. It is designed to accompany medical devices placed in the sterilizer.

The user places the packaged Verify SCBI for VH2O2 into the V-PRO 1 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. The SCBI indicates a pass if the media remains purple and non-turbid. The SCBI indicates a failure of sterilization if the media changes from purple to yellow and/or if the media is turbid.

4. Intended Use

The Verify Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes is intended as a standard method for frequent monitoring of the Amsco V-PRO 1 Low Temperature Sterilization System.

5. Description of Safety and Substantial Equivalence

The Verify SCBI for VH2O2 has the same or similar intended use, accessories, viable population, resistance characteristics, culture conditions, primary and secondary packaging, and storage conditions as compared to its predicate device the STERRAD CycleSure Biological Indicator.

Summary of Nonclinical Tests:

Test	Result
Viable Population Assay	Pass Within Specification
Resistance	Pass Within Specification
Growth Inhibition by Carrier and Pack Materials	Pass No Inhibition
Holding Time Assessment	Pass 72 Hour Hold Time Established
Effect of Media Additives	Pass No Effect of Additives
Incubation Time Validation	Pass 4 day Incubation
Effect of Sterilization Process on Recovery Media	Pass No Affect
Stability of Biological Read	Pass Stable for 7 Days
Controls	Pass Viability and Media Sterility Demonstrated
Media Volume	Pass Adequate Volume for Incubation Conditions
Throughput Indicator Color Change	Pass Color Change Demonstrated under Worst Case Exposure Conditions
Stability Evaluation	Pass On Going Stability Evaluation
Worst Case Location In V-PRO Sterilization Chamber	Pass Middle of Top Shelf is the Worst Case Location

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jack Scoville
Fellow, Regulatory Affairs
STERIS, Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

MAY 28 2008

Re: K073244
Trade/Device Name: Verify Self-Contained Biological Indicator for Vaporized VH202 Sterilization Processes
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: April 30, 2008
Received: May 1, 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.

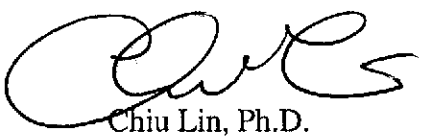
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): **K073244**

Device Name: Verify Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes

Indications For Use:

The Verify Self-Contained Biological Indicator for Vaporized VH2O2 Sterilization Processes is intended as a standard method for frequent monitoring of the Amsco® V-PRO™ 1 Low Temperature Sterilization System.

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)

Shirley A. Murphy M.D.

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

510(k) Number: K073244