K072510

STERIS®

510(k) Summary
For
Verify® V-PRO Chemical Indicator
-Versions 1 and 2-

DEC 1 1 2007

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Jack Scoville.
Fellow
Regulatory Affairs
Telephone: (440) 392-7330
Fax No: (440) 357-9198

Submission Date: September 05, 2007

1. Device Name

Trade Name: Verify® V-PRO Chemical Indicator.

Models: Version 1: Verify® V-PRO Chemical Indicator.
Version 2: Verify® V-PRO Chemical Indicator Adhesive Label.

Common Name: Chemical Indicator.

Classification Name: Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Device

Chemical Indicator Component of the STERRAD® CycleSure™ Biological Indicator (K994055)

3. Device Description

The Verify® V-PRO Chemical Indicator is used in each processing cycle to indicate exposure to an Amsco V-PRO 1 Low Temperature Sterilizer cycle. When exposed, the indicator exhibits a visible color change from magenta to yellow.

The Verify® V-PRO Chemical Indicator is provided as two formats:

- Version 1: Verify® V-PRO Chemical Indicator
- Version 2: Verify® V-PRO Chemical Indicator Adhesive Label

The Version 1: Verify® V-PRO Chemical Indicator is a Class 1 process indicator in accordance with ISO 11140-1:2005 which consists of the chemical indicator applied to an inert polymeric substrate; the indicator spot is laminated with a transparent laminate.

The Version 2: Verify® V-PRO Chemical Indicator Adhesive Label is a Class 1 process indicator in accordance with ISO 11140-1:2005 which consists of the chemical indicator applied to a spun bonded polyolefin substrate with an adhesive supplied on a backing paper.

4. Intended Use:

The Verify® V-PRO Chemical Indicator (Version 1) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2) are Class 1 vaporized hydrogen peroxide sterilization process indicators. They are designed to distinguish between

processed and unprocessed units when placed within (Version 1) or affixed to (Version 2) sterilization wraps, trays or pouches to indicate, through a visible change from magenta to yellow, when the device (Version 1) or pack (Version 2) has been exposed to a V-PRO 1 sterilization process. This product is designed for use exclusively in the Amsco V-PRO 1 Low Temperature Sterilization system at 50°C using Vaprox™ HC Sterilant.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are single use process indicators for use in monitoring Vaporized Hydrogen Peroxide sterilization cycles. The differences between the proposed Verify® V-PRO Chemical Indicator and the predicate device are limited to differences in design, material, and parameters of the sterilization cycles these indicators are designed to monitor. These differences do not raise any new issues of safety and efficacy.

6. Performance Testing

Performance testing was conducted to verify that the proposed Verify® V-PRO Chemical Indicator meets the requirements for Class 1 vaporized hydrogen peroxide sterilization indicators as defined in ANSI/AAMI ISO 11140-1:2005. Additional testing was completed to simulate typical in-use applications and testing was also performed to investigate the effects of exposure to UV, visible light and aggressive chemicals to the performance of the Verify® V-PRO Chemical Indicator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2007

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

Re: K072510
Trade/Device Name: Verify® V-PRO Chemical Indicator (Versions 1 and 2)
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: November 20, 2007
Received: November 21, 2007

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.

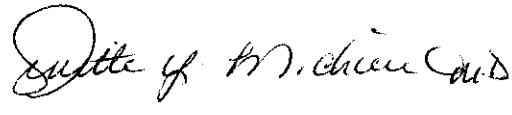
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K072510

Device Name: Verify® V-PRO Chemical Indicator (Versions 1 and 2).

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)

Shula R Murphy MD

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