STERIS®

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

OCT 2 7 2009

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

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

Submission Date: October 26, 2009

1. Device Name

Trade Name: Verify® V-PRO Chemical Indicator

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

Verify® V-PRO Chemical Indicator – Version 1 and 2 (K072510)

3. Device Description

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

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

The Version 1A: Verify® V-PRO Chemical Indicator is a Class 1 process indicator in accordance with ANSI/AAMI/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 2A: Verify® V-PRO Chemical Indicator Adhesive Label is a Class 1 process indicator in accordance with ANSI/AAMI/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. Indication for Use:

The Verify® V-PRO Chemical Indicator (Version 1A) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2A) are Class 1 vaporized hydrogen peroxide sterilization process indicators that conform to ANSI/AAMI/ISO 11140-1: 2005. They are designed to distinguish between processed and unprocessed units when placed within (Version 1A) or affixed to (Version 2A) sterilization wraps, trays or pouches to indicate, through a visible change from magenta to yellow, when the device (Version 1A) or pack (Version 2A) has been exposed to a V-PRO 1 Low Temperature sterilization process (Lumen Cycle) or V-PRO 1 Plus Low Temperature sterilization process (Lumen or Non-Lumen cycle). This product is

designed for use exclusively in the Amsco V-PRO 1 Low Temperature Sterilization System and Amsco V-PRO 1 Plus Low Temperature Sterilization System at 50 °C using Vaprox™ HC Sterilant.

The Verify® V-PRO Chemical Indicator (Version 1A) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2A) intended for use in vaporized hydrogen peroxide sterilization processes. The Verify® V-PRO Chemical Indicator (Version 1A) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2A) change color from magenta to yellow when exposed to the appropriate cycle conditions of temperature, sterilant concentration and duration, as shown in the table below:

Model	Temperature	Sterilant Concentration	Cycle Type	Exposure Time
Verify Version 1A	50 °C	2.1 g H_2O_2 x 4 injections	Lumen	32 minutes
Verify Version 2A	50 °C	2.1 g H_2O_2 x 4 injections	Lumen	32 minutes
Verify Version 1A	50 °C	2.1 g H_2O_2 x 4 injections	Non-Lumen	12 minutes
Verify Version 2A	50 °C	2.1 g H_2O_2 x 4 injections	Non-Lumen	12 minutes

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 – Version 1A and Version 2A and the predicate Verify® V-PRO Chemical Indicator – Version 1 and 2 device are limited to differences in the chemical composition of the indicator ink. 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 – Version 1A and Version 2A 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. John R. (Jack) Scoville, Jr.
Fellow, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

OCT 2 7 2009

Re: K091174
Trade/Device Name: Verify® V-PRO Chemical Indicator – Version 1A and Verision 2A
Regulation Number: 21 CFR 880. 2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: October 21, 2009
Received: October 22, 2009

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division 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): K091174

Device Name: Verify® V-PRO Chemical-Indicator – Version 1A and Version 2A

Indications For Use:

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The Verify® V-PRO Chemical Indicator (Version 1A) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2A) intended for use in vaporized hydrogen peroxide sterilization processes. The Verify® V-PRO Chemical Indicator (Version 1A) and the Verify® V-PRO Chemical Indicator Adhesive Label (Version 2A) change color from magenta to yellow when exposed to the appropriate cycle conditions of temperature, sterilant concentration and duration, as shown in the table below:

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Verify Version 2A	50 °C	2.1 g H_2O_2 x 4 injections	Lumen	32 minutes
Verify Version 1A	50 °C	2.1 g H_2O_2 x 4 injections	Non-Lumen	12 minutes
Verify Version 2A	50 °C	2.1 g H_2O_2 x 4 injections	Non-Lumen	12 minutes

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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(k)

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

510(k) Number: K091174