K140515

STERIS®

JUL 17 2014

510(k) Summary
For
VERIFY® V-PRO Chemical Indicator

Sponsor Facility

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

Manufacturing Facility

Albert Browne Ltd., a subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Bill Brodbeck
Director, Regulatory Affairs

Telephone: (440) 392-7690
Fax No: (440) 357-9198
William_brodbeck@steris.com

Submission Date: July 16, 2014

1. Device Name

Trade Name:	VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label
Models:	Version 1B: VERIFY® HPU Chemical Indicator Version 2B: VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label (Collectively referenced as the VERIFY® V-PRO Chemical Indicator)
Common Name:	Chemical Indicator
Class:	II
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800, Product Code JOJ)

2. Predicate Device

Verify® V-PRO Chemical Indicator – Version 1A and 2A (K091174)

3. Device Description

The VERIFY® V-PRO Chemical Indicator is used in each processing cycle to indicate exposure to a Lumen, Non-Lumen or Flexible Cycle in a V-PRO 1, V-PRO 1 Plus, V-PRO maX, or V-PRO 60 Low Temperature Sterilizer. When exposed to the defined processing conditions, the indicator exhibits a visible color change from magenta to yellow.

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

- Version 1B: VERIFY® HPU Chemical Indicator
- Version 2B: VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label

The Version 1B: VERIFY® HPU Chemical Indicator 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.

The Version 2B: VERIFY® Vaporized VH2O2 Process 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. Indications for Use:

The VERIFY® HPU Chemical Indicator is a Class 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units when placed within packs to be sterilized to indicate, through a visible change from magenta to yellow, when the device has been exposed to the Lumen, Non Lumen or Flexible sterilization cycle of a V-PRO® Low Temperature Sterilization System.

The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Class 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible color change from magenta to yellow, when the pack has been exposed to the Lumen, Non Lumen or Flexible sterilization cycle of a V-PRO® Low Temperature Sterilization System.

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 V-PRO Chemical Indicator – Versions 1B and 2B and the predicate VERIFY® V-PRO Chemical Indicator – Version 1A and 2A device are limited to minor physical differences as well as expanding the indications for use statement to include use in the V-PRO 60 Low Temperature Sterilization System. Testing included in this submission demonstrates that the proposed device performs as intended and is substantially equivalent to the predicate device.

6. Technological Characteristics

The proposed and predicate devices are Class 1 single use process indicators in accordance with ISO 11140-1:2005 for use in monitoring Vaporized Hydrogen Peroxide sterilization cycles. The ink, mechanism of action, and endpoint are the same and when exposed to the defined processing conditions, the proposed and predicate devices exhibit a visible color change from magenta to yellow.

Table 5-1 contains a comparison of technological characteristics and specifications of the proposed VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label to the predicate Verify® V-PRO Chemical Indicator – Version 1A and 2A.

Table 5-1. Device Comparison Table

Feature	Proposed VERIFY® V-PRO Chemical Indicator – V1B, V2B	K091174 Verify® V-PRO Chemical Indicator – V1A, V2A	Comparison
Intended use	The VERIFY® HPU Chemical Indicator is a Class 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units when placed within packs to be sterilized to indicate, through a visible change from magenta to yellow, when the device has been exposed to the Lumen, Non Lumen or Flexible sterilization cycle of a V-PRO® Low Temperature Sterilization System. The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Class 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible color change from magenta to yellow, when the pack has been exposed to the Lumen, Non Lumen or Flexible sterilization cycle of a V-PRO® Low Temperature Sterilization System.	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	The intended use statement has been rearranged for simplicity for the proposed device but conveys a similar intended use. The proposed device is intended to monitor Lumen, Non Lumen and Flexible Cycles of V-PRO 1, 1 Plus and maX Low Temperature Sterilization Systems as with the predicate device with the addition of adding the claim of use in the V-PRO 60 Low Temperature Sterilization System.

Feature	Proposed VERIFY® V-PRO Chemical Indicator – V1B, V2B	K091174 Verify® V-PRO Chemical Indicator – V1A, V2A	Comparison
Device design - components	Indicator Ink printed onto spun-bonded polyolefin (Versions 1B and 2B)	Indicator Ink printed onto Polypropylene (Version 1A) or spun-bonded polyolefin (Version 2A)	The proposed device contains the same components for versions 2A and 2B as version 1B of the predicate device.
Indicator agent	Proprietary formulation	Proprietary formulation	The indicator agent is identical to the predicate.
Sterilization method and cycles	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilizers	Vaporized Hydrogen Peroxide in the Amsco V-PRO 1 and Amsco V-PRO 1 Plus Low Temperature Sterilizers	The sterilization cycles for the V-PRO maX and V-PRO 60 are being added for the proposed device.
Mechanism of action	Proprietary	Proprietary	Mechanism of action is identical to predicate
Endpoint specifications	No Endpoint Specifications (Class 1 Process Indicator)	No Endpoint Specifications (Class 1 Process Indicator)	Same
Side by side testing with biological indicators?	No	No	Same
Specification	Conforms to ANSI/AAMI/ISO 11140-1:2005 requirements for a Class 1 Hydrogen Peroxide Chemical Indicator	Conforms to ANSI/AAMI/ISO 11140-1:2005 requirements for a Class 1 Hydrogen Peroxide Chemical Indicator	Same

7. 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.

Table 5-2 summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the proposed VERIFY® V-PRO Chemical Indicator – Version 1B and Version 2B is safe and effective. These studies confirm that the proposed device's performance meets the requirements of its pre-defined acceptance criteria and intended uses, and qualify the proposed device for use in the V-PRO 1, V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilization Systems.

Table 5-2. Verification Results Summary

Test of 6 Lots	Acceptance Criteria		Study Result
	FAIL	PASS	
Class 1 Performance Testing	100%	≥ 90%	**Pass**
V-PRO 60 Simulated Use Testing in Lumen, Non Lumen and Flexible Cycles	100%	≥ 90%	**Pass**
V-PRO maX Simulated Use Testing in Lumen, Non-Lumen and Flexible Cycles	100%	≥ 90%	**Pass**

The results of the VERIFY® V-PRO Chemical Indicator performance testing demonstrate that both formats of the device, VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label, perform as intended and the proposed device is substantially equivalent to the predicate device.

8. Conclusion

The proposed device contains the same indicator agent on the same substrate with the minor addition of the adhesive on the VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label. The indications for use vary only in the addition of claims for a new sterilizer. Testing included in this submission demonstrates that the VERIFY® V-PRO Chemical Indicator performance testing demonstrate that both formats of the device, VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label, perform as intended and the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 17, 2014

STERIS Corporation
Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
5960 Heisley Road
Mentor, OH 44060

Re: K140515
Trade/Device Name: VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label
Regulation Number: 21 CFR 880.2800
Regulation Name: Process Indicators
Regulatory Class: II
Product Code: JOJ
Dated: June 19, 2014
Received: June 20, 2014

Dear Dr. Brodbeck:

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140515

Device Name: VERIFY® HPU Chemical Indicator and
VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label

Indications For Use:

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The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Class 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible color change from magenta to yellow, when the pack has been exposed to the Lumen, Non-Lumen or Flexible sterilization cycle of a V-PRO® Low Temperature Sterilization System.

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)

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300055864, cn=Elizabeth F. Claverie -S
Date: 2014.07.15 19:14:13 -04'00'