February 9, 2018

STERIS Corporation
Bill Brodbeck
Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K172746
Trade/Device Name: VERIFY® HPU Chemical Indicator and VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: January 9, 2018
Received: January 10, 2018

Dear Bill 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172746

Device Name
VERIFY® HPU Chemical Indicator

Indications for Use *(Describe)*
The VERIFY® HPU Chemical Indicator is a Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172746

Device Name
VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label

Indications for Use *(Describe)*
The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For
VERIFY® HPU Chemical Indicator
and
VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label

K172746

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: January 23, 2018

1. Device Name

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

Models: Version 1C: VERIFY® HPU Chemical Indicator
Version 2C: VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label
(Collectively referenced as the VERIFY® V-PRO Chemical Indicator)

Common Name: Chemical Indicator

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

Class: II

2. Predicate Device

VERIFY® V-PRO Chemical Indicator (K140515)

3. Device Description

The VERIFY® V-PRO Chemical Indicator is used in each processing cycle to indicate exposure to a Lumen, Non Lumen, Flexible, or Fast Non Lumen Cycle in a V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60, or V-PRO maX 2 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 1C: VERIFY® HPU Chemical Indicator
- Version 2C: VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label

The Version 1C: VERIFY® HPU Chemical Indicator is a Type 1 process indicator in accordance with ISO 11140-1:2014 which consists of the chemical indicator applied to a spun bonded polyolefin substrate.

The Version 2C: VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 process indicator in accordance with ISO 11140-1:2014 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 Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.

The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.

5. Technological Characteristics

The proposed and predicate devices are Type 1 single use process indicators in accordance with ISO 11140-1:2014 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 1B and 2B.

Table 5-1. Device Comparison Table

Feature	Proposed VERIFY® V-PRO Chemical Indicator – V1C, V2C	K140515 VERIFY® V-PRO Chemical Indicator – V1B, V2B	Comparison
Intended use	The VERIFY® HPU Chemical Indicator is a Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System. The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is a Type 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, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.	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 Intended Use has been modified in the proposed device in order to include the Fast Non Lumen Cycle of the V-PRO maX 2 device. Also, the indicator reference has changed from Class 1 to Type 1 based upon updates to the guiding standard (ANSI/AAMI/ISO 11140-2014).
Device design - components	Indicator Ink printed onto spun-bonded polyolefin (Version 1C) and spun-bonded polyolefin with an adhesive and a glassine backing (Version 2C).	Indicator Ink printed onto spun-bonded polyolefin (Version 1B) and spun-bonded polyolefin with an adhesive and a glassine backing (Version 2B).	The proposed device contains the same components for versions 1C and 2C as versions 1B and 2B of the predicate device, respectively.
Indicator agent	Proprietary formulation	Proprietary formulation	The indicator agent is identical to the predicate.

Feature	Proposed VERIFY® V-PRO Chemical Indicator – V1C, V2C	K140515 VERIFY® V-PRO Chemical Indicator – V1B, V2B	Comparison
Sterilization method and cycles	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60 and V-PRO maX 2 Low Temperature Sterilizers	Vaporized Hydrogen Peroxide in the V-PRO 1 and V-PRO 1 Plus, V-PRO maX and V-PRO 60 Low Temperature Sterilizers	The sterilization cycles for the V-PRO maX 2 are being added for the proposed device.
Mechanism of action	Proprietary	Proprietary	Mechanism of action is identical to predicate
Endpoint specifications	No Endpoint Specifications (Type 1 Process Indicator)	No Endpoint Specifications (Type 1 Process Indicator)	Same
Side by side testing with biological indicators?	No	No	Same
Specification	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a Type 1 Hydrogen Peroxide Chemical Indicator	Conforms to ANSI/AAMI/ISO 11140-1:2005 requirements for a Class 1 Hydrogen Peroxide Chemical Indicator	Proposed device conforms to the most recent standard.

6. Performance Testing

Performance testing was conducted to verify that the proposed VERIFY® V-PRO Chemical Indicator meets the requirements for Type 1 vaporized hydrogen peroxide sterilization indicators as defined in ANSI/AAMI/ISO 11140-1:2014. 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 1C and Version 2C 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, V-PRO 60 and V-PRO maX 2 Low Temperature Sterilization Systems.

Table 5-2. Verification Results Summary

Test of 6 Lots	Acceptance Criteria		Study Result
	FAIL	PASS	
Type 1 Performance Testing	100%	≥ 90%	**Pass**
V-PRO maX 2 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.

7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and perform at least as well as the legally marketed predicate device (K140515, Class II (21 CFR 880.2800), product code JOJ.