February 9, 2018

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

Re: K172753
Trade/Device Name: VERIFY VH2O2 Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: January 9, 2017
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)*
K172753

Device Name
VERIFY VH2O2 Indicator Tape

Indications for Use *(Describe)*

The VERIFY™ VH2O2 Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The VERIFY™ VH2O2 Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

The tape may be used in the following sterilization cycles:
- Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers
- Standard Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer
- Express, Flex Scope, Duo and Standard Cycles of the STERRAD® 100 NX Sterilizer

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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STERIS®

510(k) Summary
for
VERIFY™ VH2O2 Indicator Tape
K172753

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (216) 354-2600
Fax No: (216) 639-4459

Contact: Bill Brodbeck
Director, Regulatory Affairs
Telephone: (440) 392-7690
Fax No: (440) 357-9198
E-mail: William_brodbeck@steris.com

Submission Date: September 11, 2017

1. Device Name

Trade Name:	VERIFY™ VH2O2 Indicator Tape
Common/Usual Name:	Chemical Sterilization Process Indicator
Classification Name:	Sterilization Process Indicator (21 CFR 880.2800, JOJ)
Classification:	Class II

2. Predicate Device

VERIFY™ VH2O2 Indicator Tape (K160485)

3. Description of Device

The VERIFY VH2O2 Indicator Tape consists of a special coated crepe paper with diagonal lines of a chemical indicator specific for hydrogen peroxide sterilization. It meets the performance specifications for a Type 1 process indicator as defined in ANSI/AAMI/ISO 11140-1:2014.

The VERIFY VH2O2 Indicator Tape and its packaging are manufactured in the absence of lead, heavy metals, natural rubber latex and dry natural rubber.

4. Intended Use/ Indications for Use

The VERIFY™ VH2O2 Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The VERIFY™ VH2O2 Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

The tape may be used in the following sterilization cycles:

- Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers
- Standard Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer
- Express, Flex Scope, Duo and Standard Cycles of the STERRAD® 100 NX Sterilizer

Table 5.1 Indications for Use Comparison

Proposed VERIFY VH2O2 Indicator Tape	Predicate (K160485) VERIFY VH2O2 Indicator Tape	Comparison
The VERIFY™ VH2O2 Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The VERIFY™ VH2O2 Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches. The tape may be used in the following sterilization cycles: • Non Lumen, Flexible, Lumen and Fast Non Lumen Cycles of the V-PRO 1, 1 Plus, maX, 60 and maX 2 Sterilizers • Standard Cycle of the STERRAD® 100S Sterilizer • Standard and Advanced Cycles of the STERRAD® NX Sterilizer • Express, Flex Scope, Duo and Standard Cycles of the STERRAD® 100 NX Sterilizer	The VERIFY VH2O2 Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The tape may be used in the following sterilization cycles: • Non Lumen, Flexible and Lumen Cycles of the V-PRO 1, 1 Plus, maX and 60 Low Temperature Sterilizers • Standard Cycle of the STERRAD® 100S Sterilizer • Standard and Advanced Cycles of the STERRAD® NX Sterilizer Express, Flex Scope, Duo and Standard Cycles of the STERRAD® 100 NX Sterilizer	The Indications for Use has been modified in the proposed device in order to include the Fast Non Lumen Cycle of the V-PRO maX 2 device. The proposed device also includes the statement that the VERIFY™ VH2O2 Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

5. Description of Safety and Substantial Equivalence

The VERIFY VH2O2 Indicator Tape has equivalent characteristics as compared to its predicate device. **Table 5.2** compares the proposed device's design to the predicate.

Table 5.2 Device Comparison

Characteristic	Proposed	Predicate	Comparison
Substrate	Crepe Paper	Crepe Paper	Same
Indicator	Proprietary – conforms with ISO 11140-1:2014 Type 1 requirements	Proprietary – conforms with ISO 11140-1:2014 Type 1 requirements	Same
Adhesive	Proprietary	Proprietary	Testing included in this submission demonstrating

Characteristic	Proposed	Predicate	Comparison
			performance (See Table 5.3).
Color Change	Pink to Peach/Yellow	Pink to Peach/Yellow	Same
Detection	hydrogen peroxide dose	hydrogen peroxide dose	Same
Shelf-life	18 months	18 months	Same
Storage Conditions	16 – 24°C, 30 - 60% RH	16 – 24°C, 30 - 60% RH	Testing included in this submission to support proposed device's shelf life when stored under labeled conditions (See Table 5.3).

Since the VERIFY VH2O2 Indicator Tape is identical to the predicate device, prior nonclinical testing (K160485) is referenced in this submission to support performance of the chemical indicator in accordance to the vapor-phased hydrogen peroxide, Type 1 chemical indicator requirements in ANSI/AAMI/ISO 11140-1:2014. Furthermore, since the proposed device is identical to the proposed device, testing was provided in K160485 addresses endpoint stability, light stability, biocompatibility and adhesion. To demonstrate that the CI performs appropriately according to the proposed device's expanded claims, performance was tested in the V-PRO maX 2's Fast Non Lumen Cycle with loads under simulated use conditions under pass and fail conditions. Shelf-life testing evaluated CI performance per ANSI/AAMI/ISO 11140-1:2014, endpoint color stability and tape adhesion after various times of storage within the labeled storage conditions. **Table 5.3** summarizes the testing performed in the current submission.

Table 5.3 Summary of Nonclinical Tests:

Test	Result
Simulated Use Testing in Fast Non Lumen Cycle	Pass
Stability Testing for 18 month Shelf Life	Pass

6. 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 K160485, Class II (21 CFR 880.2800), product code JOJ.