



Food and Drug Administration
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June 1, 2016

Steris Corporation
Anthony Piotrkowski
Senior Manager, Regulatory Affairs
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Mentor, Ohio 44060

Re: K160485

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: April 29, 2016
Received: May 2, 2016

Dear Mr. Piotrkowski:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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Enclosure

Indications for Use

510(k) Number (if known)

K160485

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 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

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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510(k) Summary
for
VERIFY™ VH2O2 Indicator Tape

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Submission Date: May 28, 2016

K160485

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

VERIFY™ VH2O2 Indicator Tape

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)

2. Predicate Device

STERRAD® Sealsure™ Chemical Indicator Tape (K111519)

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 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

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
VERIFY™ [VH2O2] Indicator Tape

Table 5.1 Indications for Use Comparison

Proposed VERIFY [VH2O2] Indicator Tape	Predicate (K111519) STERRAD SEALSURE Chemical Indicator Tape	Comparison
<p>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:</p> <ul style="list-style-type: none"> • 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 	<p>STERRAD SEALSURE Chemical Indicator Tape (PN 14202) is a process indicator (ISO 11140-1:2205) intended for use by healthcare providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD Sterilization Systems.</p> <ul style="list-style-type: none"> • Standard Cycle of STERRAD 100S • Standard Cycle of STERRAD 50 • Standard Cycle of STERRAD 200 • Standard and Advanced Cycles of STERRAD NX • Standard, Flex, DUO and EXPRESS Cycles of STERRAD 100NX <p>The color of the STERRAD SEALSURE Chemical Indicator Tape changes from red to gold (or lighter) when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads.</p>	<p>Both devices are chemical indicator tapes used to secure packs for sterilization in hydrogen peroxide sterilizers and to indicate through a color change that the packs have been exposed to hydrogen peroxide. Testing is included in this submission to demonstrate safe and effective performance of the proposed device in the indicated cycles.</p>

5. Description of Safety and Substantial Equivalence

The VERIFY [VH2O2] Indicator Tape has equivalent characteristics as compared to its predicate device, STERRAD® Sealsure™ Chemical Indicator Tape. **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 11140-1:2005 Class 1 requirements	Testing included in this submission demonstrating performance (See Table 5.3).
Adhesive	Proprietary	Proprietary	Testing included in this submission demonstrating performance (See Table 5.3).
Color Change	Pink to Peach/Yellow	Red to Gold	Similar start and endpoint colors
Detection	hydrogen peroxide dose	hydrogen peroxide dose	Same
Shelf-life	3 months to be extended as real time data allows to a projected 24 months	22 months	Testing included in this submission to support proposed device’s shelf life when stored under labeled conditions (See Table 5.3).
Storage Conditions	16 – 24°C, 30 - 60% RH	15 – 30°C, Dry Conditions	

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

VERIFY™ [VH2O2] Indicator Tape

The VERIFY [VH2O2] Indicator Tape was tested in nonclinical testing. Performance of the chemical indicator, CI, was demonstrated by testing in an ANSI/AAMI/ISO 18472:2006-conforming resistometer according to the vapor-phased hydrogen peroxide, Type 1 chemical indicator requirements in ANSI/AAMI/ISO 11140-1:2014. CI performance was also tested in hydrogen peroxide sterilizers (V-Pro and STERRAD) with loads under simulated use conditions under pass and fail conditions. Endpoint stability was tested by evaluating the color of processed tape at various time points when stored at room temperature. Light stability was demonstrated by evaluating the tape after storage outside its packaging before exposure to peroxide sterilization. Tape adhesion was evaluated using ASTM adhesion standard and under simulated use conditions on wrapped loads processed through the sterilizer. Biocompatibility was demonstrated by testing peroxide residual levels of processed tape samples and Off-set testing per ANSI/AAMI/ISO 11140-1:2014. Shelf-life testing evaluated CI performance per ANSI/AAMI/ISO 11140-1:2014 and tape adhesion after various times of storage within the labeled storage conditions. **Table 5.3** summarizes the testing performed to demonstrate substantial equivalence.

Table 5.3 Summary of Nonclinical Tests:

Test	Result
ANSI/AAMI/ISO 11140-1:2014 Vaporized Hydrogen Peroxide Process Indicator Performance Testing	Pass
Simulated Use: Pass Performance Testing	Pass
Simulated Use: Fail Performance Testing	Pass
Endpoint Stability	Pass
Light Stability after Removal from Packaging	Pass
Adhesion Evaluation	Pass
Shelf Life Evaluation	Pass
Hydrogen Peroxide Residual Testing	Pass
Off-set (transference) Performance Testing	Pass

6. Conclusion

The VERIFY [VH2O2] Indicator Tape is substantially equivalent to the predicate device, STERRAD® Sealsure™ Chemical Indicator Tape. Based on the performance testing provided in this submission and summarized above, the subject device is as safe and as effective as the legally marketed, claimed predicate device.