May 29, 2018

Steris Corporation
Marcia Benedict
Senior Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K180553
Trade/Device Name: VERIFY Spore Test Strip for S40 Sterilant
Regulation Number: 21 CFR 880.6887
Regulation Name: Spore Test Strip
Regulatory Class: Class II
Product Code: OVY
Dated: February 28, 2018
Received: March 1, 2018

Dear Marcia Benedict:

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,

Geeta K.
Pamidimukkala -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180553

Device Name
VERIFY® Spore Test Strip for S40® Sterilant

Indications for Use *(Describe)*

The VERIFY® Spore Test Strip for S40 Sterilant is intended to provide users with a means to assess spore kill by S40 sterilant use dilution in the STERIS automated Liquid Chemical Sterilant Processing Systems (SYSTEM 1E Liquid Chemical Sterilant Processing System and SYSTEM 1 endo Liquid Chemical Sterilant Processing System). A "no growth" result from the VERIFY Spore Test Strip for S40 Sterilant after 24 hours of incubation indicates that the liquid chemical sterilization process achieved the conditions necessary to kill at least 1 x 10E5 viable spores (5 logs) on the test strip. It does not confirm the expected full performance of the liquid chemical sterilization cycle.

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® SPORE TEST STRIP
for S40® STERILANT

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Submission Date: May 22, 2018

Premarket Notification Number: K180553

1. Device Name

Trade Name:	VERIFY® Spore Test Strip for S40 Sterilant
Models:	N/A
Common Name:	Spore Test Strip
Classification Name:	Liquid Chemical Processing System
Classification	21 CFR 880.6887
Product Code	OVY

2. Predicate Device

VERIFY® Spore Test Strip for S40 – DEN110002 (K100049)

3. Device Description

The VERIFY® Spore Test Strip for S40 Sterilant consists of a 1 ⅜ in. x ¼ in. filter paper-based strip inoculated with *Geobacillus stearothermophilus* spores and is enclosed in a glassine envelope. The Spore Test Strips are provided with media vials containing a modified tryptic soy broth with phenol red pH indicator, and a transfer clip. Using the clip, the Spore Test Strip is secured on the available post located in the tray of the liquid chemical sterilant processor. The transfer clip thus holds the Spore Test Strip in a fixed location during a processing cycle in the STERIS Liquid Chemical Sterilant Processing System and enables aseptic transfer of the strip from the processor into the growth media vial after the cycle ends.

For use, the Spore Test Strip is removed from the glassine envelope and secured using the transfer clip in the SYSTEM 1E Liquid Chemical Sterilant Processing System or SYSTEM 1 endo Liquid Chemical Sterilant Processing System along with the items to be liquid chemically sterilized. The liquid chemical sterilization cycle is initiated. At the end of the full cycle, the Spore Test Strip is removed and placed into the vial of growth medium for incubation under the specified conditions that will promote spore growth for at least 24 hours. If the media remains red and non-turbid, the user interprets the results as a pass. If the media color turns yellow or is turbid, the user interprets the result as a fail.

The Spore Test Strip is incubated at 55-60ºC for a minimum of 24 hours, but may be incubated for up to 7 days. The shelf life is 12 months when stored at 2-24°C and 30-80% relative humidity (RH) away from sterilizing agents and excessive heat.

The current submission makes no changes to the strip itself; only the indications for use are changing to encompass the VERIFY Spore Test Strip's broader use in more than one STERIS automated liquid chemical sterilant processing system (SYSTEM 1E Liquid Chemical Sterilant Processing System and SYSTEM 1 endo Liquid

Chemical Sterilant Processing System) that uses S40 Sterilant Concentrate under identical exposure conditions.

4. Intended Use:

The VERIFY® Spore Test Strip for S40 Sterilant is intended to provide users with a means to assess spore kill by S40 sterilant use dilution in the STERIS automated Liquid Chemical Sterilant Processing Systems (SYSTEM 1E Liquid Chemical Sterilant Processing System and SYSTEM 1 endo Liquid Chemical Sterilant Processing System). A "no growth" result from the VERIFY Spore Test Strip for S40 Sterilant after 24 hours of incubation indicates that the liquid chemical sterilization process achieved the conditions necessary to kill at least 1 x 10^5 viable spores (5 logs) on the test strip. It does not confirm the expected full performance of the liquid chemical sterilization cycle.

5. Technological Characteristic Comparison Table

The proposed device and its predicate are physically identical. The liquid chemical sterilant exposure conditions monitored are identical.

The revised indication for use statement will enable use of the VERIFY Spore Test Strip for S40 Sterilant in a STERIS automated liquid chemical sterilant processor that uses S40 Sterilant Concentrate in an identical controlled cycle. This will facilitate the indicator's intended use in the SYSTEM 1E Liquid Chemical Sterilant Processing System and the SYSTEM 1 endo Liquid Chemical Sterilant Processing System.

Table 1. Device Comparison Table

Feature	K180553 VERIFY Spore Test Strip for S40 Sterilant	Predicate DEN110002 VERIFY Spore Test Strip for S40	Comparison
Intended use	The VERIFY® Spore Test Strip for S40 Sterilant is intended to provide users with a means to assess spore kill by S40 sterilant use dilution in the STERIS automated Liquid Chemical Sterilant Processing Systems (SYSTEM 1E Liquid Chemical Sterilant Processing System and SYSTEM 1 endo Liquid Chemical Sterilant Processing System). A "no growth" result from the VERIFY Spore Test Strip for S40 Sterilant after 24 hours of incubation indicates that the	The Verify Spore Test Strip for S40 is intended to provide users with a means to assess spore kill by S40 sterilant use dilution in the SYSTEM 1E Liquid Chemical Sterilant Processing System. A "no growth" result from the VERIFY Spore Test Strip for S40 after 24 hours of incubation indicates that the liquid chemical sterilization process achieved the conditions necessary to kill at least 1 x 10^5 viable spores (5 logs) on the test strip. It does not confirm the expected full performance of the SYSTEM 1E	The proposed rewording describes the sterilant and the liquid chemical sterilization cycle the Spore Test Strip assesses rather than citing one processor by name.

Feature	K180553 VERIFY Spore Test Strip for S40 Sterilant	Predicate DEN110002 VERIFY Spore Test Strip for S40	Comparison
	liquid chemical sterilization process achieved the conditions necessary to kill at least 1 x 10^5 viable spores (5 logs) on the test strip. It does not confirm the expected full performance of the liquid chemical sterilization cycle.	Liquid Chemical Sterilization Cycle.	
Organism	*Geobacillus stearothermophilus* 7953 spores	*Geobacillus stearothermophilus* 7953 spores	Identical
Viable Spore Population	At manufacture: ≥1.5 x 10^5 CFU Post-Builders: ≥ 1.0 x 10^5 CFU	At manufacture: ≥1.5 x 10^5 CFU Post-Builders: ≥ 1.0 x 10^5 CFU	Identical
Resistance characteristics	At 1635 ppm PAA: • D-value 12 – 26 seconds • Survival Time ≥ 38 seconds • Kill Time ≥ 239 seconds	At 1635 ppm PAA: • D-value 12 – 26 seconds • Survival Time ≥ 38 seconds • Kill Time ≥ 239 seconds	Identical
LCSPS cycle parameters	• >1820 mg/L PAA • 6 minutes • 45.5 – 60°C	• >1820 mg/L PAA • 6 minutes • 45.5 – 60°C	Identical
Culture Conditions	• Trypticase Soy Broth Based Media • Incubation Temp.: 55-60°C • Incubation Time: 24 hours minimum; up to 7 days	• Trypticase Soy Broth Based Media • Incubation Temp: 55-60°C • Incubation Time: 24 hours minimum; up to 7 days	Identical
Carrier Material	Filter paper	Filter paper	Identical
Primary Packaging	• 20 BIs in Glassine • 20 Media Vials	• 20 BIs in Glassine • 20 Media Vials	Identical
Shelf Life	12 months	12 months	Identical

6. Description of Spore Strip Specifications:

The proposed device and its predicate are physically identical. The liquid chemical sterilant exposure conditions monitored by the strip are identical.

Table 1 demonstrates the validated populations, resistance characteristics, and reduced incubation time the predicate Spore Test Strips maintain over the product's labeled use life of 12 months when stored at 2-24°C and 30-80% relative humidity.

Table 1. Spore Test Strip Specifications *

Value	Spore Test Strip for S40
Population	
• At manufacture	≥ 1.5 x 10^5 cfu/strip
• After wash-off (end of cycle)	≥ 1.0 x 10^5 cfu/strip
Resistance	
• D-value	12-26 sec at 1635 ppm PAA
• Survival Time	≥ 38 seconds
• Kill Time	≤ 239 seconds
Reduced Incubation Time	24 hours

*cfu = colony forming units, ppm = parts per million, PAA = peracetic acid

7. Summary of Non-Clinical Testing

Table 2 summarizes non-clinical testing performed on the device. Based on the testing results from the simulated use, stability of media color, reduced Incubation Time, and the shelf life testing the device demonstrated it met the acceptance criteria for each test.

Table 2. Performance Testing on Predicate

Testing	Results
Simulated Use	PASS
Stability of Media Color	PASS
Reduced Incubation Time	PASS
Shelf Life for 12 months	PASS

8. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs at least as well as the legally marketed predicate device (DEN110002), Class II (CFR 880.6887), product code OVY.