September 11, 2023

Steris Corporation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K231746
Trade/Device Name: VERIFY Spore Test Strip for S40 Sterilant Concentrate
Regulation Number: 21 CFR 880.6887
Regulation Name: Spore Test Strip
Regulatory Class: Class II
Product Code: OVY
Dated: June 15, 2023
Received: June 15, 2023

Dear Gregory Land:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231746

Device Name
VERIFY SPORE TEST STRIP for S40 STERILANT CONCENTRATE

Indications for Use *(Describe)*
The VERIFY Spore Test Strip for S40 Sterilant Concentrate 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 and SYSTEM 1 endo Liquid Chemical Sterilant Processing Systems and enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System). A “no growth” result from the VERIFY Spore Test Strip for S40 Sterilant Concentrate after 24 hours of incubation indicates that the liquid chemical sterilization process achieved the conditions necessary to kill at least 1 x 105 viable spores (5 logs) on the spore test strip (STS). 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 CONCENTRATE
K231746

STERIS Corporation
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Lead Regulatory Affairs Specialist
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Submission Date: June 15, 2023

Submission Number: K231746

1. Device Name

Trade Name:	VERIFY Spore Test Strip for S40 Sterilant Concentrate
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 Sterilant – K180553

3. Device Description

The Spore Test Strip for S40 Sterilant Concentrate (STS) 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 STS are provided with media vials containing a modified tryptic soy broth with phenol red pH indicator, and a transfer clip. The transfer clip is used to remove the STS from the glassine envelope and serves to hold the strip in a fixed location in either the enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System (enspire CLCSPS) or the SYSTEM 1E or SYSTEM 1 endo Liquid Chemical Sterilant Processing system. After the cycle concludes, the transfer clip is used to aseptically transfer the STS from the processor into the growth media for incubation at 55-60ºC for a minimum of 24 hours but may be incubated for up to 7 days. 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 shelf life is 12 months when stored at 2-24°C and 30-80% relative humidity (RH) away from sterilizing agents and excessive heat.

There are no changes to the strip itself for this submission; only the indications for use and consequently, labeling are changing to include the Spore Test Strip's use in the STERIS enspire CLCSPS, which uses S40 Sterilant Concentrate.

4. Intended Use/Indications for Use:

The VERIFY Spore Test Strip for S40 Sterilant Concentrate is intended to provide users with a means to assess spore kill by S40 Sterilant Concentrate use dilution in the STERIS automated Liquid Chemical Sterilant Processing Systems (SYSTEM 1E and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems and enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System). A "no growth" result from the VERIFY Spore Test Strip for S40 Sterilant Concentrate 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 spore test strip (STS). It does not confirm the expected full performance of the liquid chemical sterilization cycle.

5. Description of Technological Similarities and Differences

The proposed device and its predicate are physically identical. The liquid chemical sterilant exposure conditions monitored are identical. **Table 1** summarizes the predicate and subject device comparison in tabular format.

The revised indications for use statement will enable use of the VERIFY Spore Test Strip for S40 Sterilant Concentrate in the enspire CLCSPS which uses S40 Sterilant Concentrate with critical parameters identical to those in the SYSTEM 1E Liquid Chemical Sterilant Processing System and the SYSTEM 1 endo Liquid Chemical Sterilant Processing System, previously cleared for use with the STS.

Table 1. Device Comparison Table

Feature	Proposed VERIFY Spore Test Strip for S40 Sterilant Concentrate	Predicate K180553 VERIFY Spore Test Strip for S40	Comparison
Intended use/ Indications for Use	The VERIFY Spore Test Strip for S40 Sterilant Concentrate is intended to provide users with a means to assess spore kill by S40 Sterilant Concentrate use dilution in the STERIS automated Liquid Chemical Sterilant Processing Systems (SYSTEM 1E and SYSTEM 1®endo Liquid Chemical Sterilant Processing Systems and enspire 3000 Series Cleaning and Liquid Chemical Sterilant Processing System). A "no growth" result from the VERIFY Spore Test Strip for S40 Sterilant Concentrate 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 spore test strip (STS). It does not confirm the expected full performance of the liquid chemical sterilization cycle.	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.	The proposed Indications for use are expanded to include the enspire CLCSPS. The Indications have been altered to include the enspire processor as well as the previously cleared processors. The words "Concentrate" and "spore" are inserted into the proposed Indications to ensure precision in communication.
Organism	*Geobacillus stearothermophilus* 7953 spores	*Geobacillus stearothermophilus* 7953 spores	Identical

Feature	Proposed VERIFY Spore Test Strip for S40 Sterilant Concentrate	Predicate K180553 VERIFY Spore Test Strip for S40	Comparison
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 Safety and Substantial Equivalence

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

This submission revises the product's indications for use and consequently, labeling, expanding its indications for use to include the enspire CLCSPS that provides identical S40 Sterilant Concentrate exposure conditions in a unique flow pattern.

7. Performance Testing

While the sterilant exposure conditions in the enspire are identical to the sterilant exposure conditions in the previously cleared processors, the flow rates the STS are exposed to are different. Testing, described in this submission, was undertaken to ensure safety and efficacy in the enspire CLCSPS. Refer to **Table 2**.

Table 2. Performance Testing on Subject Device

Testing	Summary	Conclusion
Population Wash Off Stability	Evaluate the population of the spores remaining on the STS after processing without sterilant.	PASS
Simulated Use	Demonstrate the STS functions appropriately in the enspire CLSPS.	PASS
Bacteriostasis	Ensure no inhibitory effects on the outgrowth of a low number of spores.	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 (K180553), Class II (CFR 880.6887), product code OVY.