December 15, 2023

STERIS Corporation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K233682
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: November 16, 2023
Received: November 16, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Allan Guan -S

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

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233682

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.

510(k) Summary
For
K233682
VERIFY SPORE TEST STRIP
for S40 STERILANT CONCENTRATE

STERIS Corporation
5960 Heisley Road
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(440) 354-2600

Contact Gregory Land
Lead Regulatory Affairs Specialist
(440) 392-7424

Summary Date December 13, 2023

1. Device Name

Trade Name:	VERIFY Spore Test Strip for S40 Sterilant Concentrate
Device Classification:	II
Common Name:	Spore Test Strip
Classification Name:	Liquid Chemical Processing System
Classification Panel:	General Hospital and Personal Use Devices Panel
Classification Number:	21 CFR 880.6887
Product Code	OVY

2. Predicate Device

VERIFY Spore Test Strip for S40 Sterilant – K231746

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 an expansion to the exposure time to the chemical sterilant.

4. Intended 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. Technological Characteristic Comparison Table

The modified device and its predicate are physically identical. The only difference is the modified device has an expanded contact time with the liquid chemical sterilant. **Table 1** summarizes the predicate and subject device comparison in tabular format.

Table 1. Device Comparison Table

Feature	Modified VERIFY Spore Test Strip for S40 Sterilant Concentrate	Predicate K231746 VERIFY Spore Test Strip for S40 Sterilant Concentrate	Comparison
Intended 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 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 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 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.	Identical
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

Feature	Modified VERIFY Spore Test Strip for S40 Sterilant Concentrate	Predicate K231746 VERIFY Spore Test Strip for S40 Sterilant Concentrate	Comparison
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 (+ up to 9 minute and 30 second Warm/Mix Phase) • 45.5 – 60°C	• >1820 mg/L PAA • 6 minutes • 45.5 – 60°C	Similar
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. Summary of Non-Clinical Testing

Shown in **Table 2** is the new testing which was performed to evaluate the modified device.

Table 2. Summary of verification activities.

Test	Acceptance Criteria	Result
Population Wash Off Testing	The modification does not affect the performance of the device.	Pass
Bacteriostasis Testing	The modification does not affect the performance of the device.	Pass

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K231746), Class II (21 CFR 880.6887), product code OVY.