December 8, 2023

Steris
Anthony Piotrkowski
Director Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K233654
Trade/Device Name: VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 14, 2023
Received: November 14, 2023

Dear Anthony 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 (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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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)*

K233654

Device Name

VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems

Indications for Use *(Describe)*

The VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is a peracetic acid concentration indicator for routine monitoring of SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems that employ S40 Sterilant Concentrate in a controlled cycle.
The unprocessed Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, the indicator changes color from blue through an intermediate beige and then to the endpoint color, pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 sterilant use dilution.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For
VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600

Contact: Tony Piotrkowski
Director, Regulatory Affairs
Telephone: (440) 392-7437
Email: tony_piotrkowski@steris.com

Submission Date: December 7, 2023

Premarket Notification Number; K233654

1. Device Name

Trade Name: VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems

Models: LCC016

Common Name: Chemical Indicator.

Classification Name: Physical/chemical sterilization process indicator

Classification 21 CFR 880.2800

Product Code JOJ

2. Predicate Device

VERIFY® Chemical Indicator for SYSTEM 1E Processor (K173428)

3. Device Description

The VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is a single-use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The indicator is covered by a clear, sterilant-permeable laminate to protect the strip from damage during handling and prevent the indicator ink from leaching from the substrate. The indicator monitors the peracetic acid (PAA) concentration of the STERIS S40 Sterilant Concentrate at the point of use in an automated liquid chemical sterilant processing system that uses S40 Sterilant Concentrate and provides a controlled 6-minute exposure at 45.5 – 60ºC during a processing cycle.

4. Intended Use/Indications for Use:

The VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is a peracetic acid concentration indicator for routine monitoring of SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems that employ S40 Sterilant Concentrate in a controlled cycle.

The unprocessed Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, the indicator changes color from blue through an intermediate beige and then to the endpoint color, pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 sterilant use dilution.

5. Description of Technological Characteristics

The proposed device and its predicate are physically identical. The more descriptive intended use statement will identify use of the Chemical Indicator in specific STERIS automated liquid chemical sterilant processors that use S40 Sterilant Concentrate. This includes the indicator's intended use in the SYSTEM 1E Liquid Chemical Sterilant Processing System and the SYSTEM 1 endo Liquid Chemical Sterilant Processing System.

The proposed device, like the predicate, indicates exposure to a targeted effective concentration of peracetic acid by a color change from blue through intermediate beige and then pink endpoint color when exposed for 6 minutes to concentrations of peracetic acid greater than 1820 ppm at 45.5 – 60ºC during the liquid chemical sterilant processing system's standard cycle.

Table 1. Device Comparison Table for Modified Chemical Indicator and Predicate

Feature	Proposed VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems	Predicate K173428 VERIFY Chemical Indicator for S40 Sterilant	Comparison
Intended use	The VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is a peracetic acid concentration indicator for routine monitoring of SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems that employ S40 Sterilant Concentrate in a controlled cycle. The unprocessed Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, the indicator changes color from blue through an intermediate beige and then to the endpoint color, pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 sterilant use dilution.	The VERIFY® Chemical Indicator for S40 Sterilant is a peracetic acid concentration indicator for routine monitoring of STERIS automated liquid chemical sterilant processing systems that employ S40 Sterilant Concentrate in a controlled cycle. The unprocessed VERIFY® Chemical Indicator for S40 Sterilant is blue. When exposed in a STERIS automated liquid chemical sterilant processor to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution during a controlled 6-minute exposure at 45.5 – 60°C, the indicator changes color from blue through an intermediate beige and then to the endpoint color, pink. The indicator may become more pink when exposed to higher peracetic acid concentrations in S40 sterilant use dilution.	The proposed rewording focuses on the specific processors which the CI is intended to monitor.

Feature	Proposed VERIFY® Chemical Indicator for SYSTEM 1E® and SYSTEM 1® endo Liquid Chemical Sterilant Processing Systems	Predicate K173428 VERIFY Chemical Indicator for S40 Sterilant	Comparison
Device design - components	Printed indicator ink printed onto polypropylene overlaid with a clear, permeable laminate	Printed indicator ink printed onto polypropylene overlaid with a clear, permeable laminate	Identical
Indicator agent	Lissamine green B (active dye) and savinyl orange (background dye)	Lissamine green B (active dye) and savinyl orange (background dye)	Identical
Mechanism of action	Bleaching of lissamine green B dye as a result of oxidation, resulting in blue to beige/pink color change.	Bleaching of lissamine green B dye as a result of oxidation, resulting in blue to beige/pink color change.	Identical
Peracetic acid concentration for the endpoint color change	> 1820 mg/L PAA	> 1820 mg/L PAA	Identical
Disposable	Yes	Yes	Identical
Shelf-life	2 years	2 years	Identical
Open bottle shelf life	6 months	6 months	Identical

6. Performance Testing

No new testing was performed for this submission. This submission revises the product's name, indications for use and, consequently, labeling to list specific liquid chemical processing systems where the CI can be used, changes that raise no new questions of safety or effectiveness.

7. 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 safely and effectively as the legally marketed predicate device (K173428), Class II (CFR 880.2800), product code JOJ.