May 2, 2025

STERIS Corporation
Steven Deline
Sr. Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K251048
Trade/Device Name: Rapicide PA High-Level Disinfection Test Strip Model Ref # = ML02-0118
Regulation Number: 21 CFR 880.2800(b)
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: April 2, 2025
Received: April 3, 2025

Dear Steven Deline:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.05.02 16:26:51 -04'00'

for: Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control 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.

510(k) Number *(if known)*
K251048

Device Name
Rapicide PA High-Level Disinfection Test Strip
Model Ref # = ML02-0118

Indications for Use *(Describe)*

The RAPICIDE™ PA Test Strips are chemical indicators used after the disinfection cycle to ensure that the RAPICIDE™ PA High-Level Disinfectant solution is met the minimum recommended concentration of 850ppm peracetic acid. The RAPICIDE PA Test Strips are designed for use by trained personnel who reprocess endoscopes and their accessories in facilities where endoscopies are performed.

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.

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K251048
510(k) Summary
For
Rapicide PA High-Level Disinfection Test Strips

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Steve Deline, MS RAS
Sr. Manager, Regulatory Affairs

Telephone: 952-767-7386
e-mail: steve_deline@steris.com

Summary Date: May 1, 2025

1. Device Name

Trade Name: Rapicide PA High-Level Disinfectant Test Strips
Model Ref # ML02-0118
Device Class: Class II
Common/usual Name: Chemical Indicator
Classification Name: Physical/Chemical sterilization process
Classification Number: indicator 21 CFR 880.2800
Product Code: JOJ

2. Predicate Device

K152394 Rapicide PA High-Level Disinfectant Test Strips

Table 1. Device Comparison Table

Feature	Predicate Device K152394	Rapicide PA HLD Test Strips (Proposed device)	Comparison
Indications for Use	The RAPICIDE™ PA Test Strips are chemical indicators used after the disinfection cycle to ensure that the RAPICIDE™ PA High-Level Disinfectant solution is met the minimum recommended concentration of 850ppm peracetic acid. The RAPICIDE PA Test Strips are designed for use by trained personnel who reprocess endoscopes and their accessories in facilities where endoscopies are performed.	The RAPICIDE™ PA Test Strips are chemical indicators used after the disinfection cycle to ensure that the RAPICIDE™ PA High-Level Disinfectant solution is met the minimum recommended concentration of 850ppm peracetic acid. The RAPICIDE PA Test Strips are designed for use by trained personnel who reprocess endoscopes and their accessories in facilities where endoscopies are performed.	Identical
Minimum Recommended Concentration	Measures the disinfectant use solution concentration above 850ppm PAA	Measure the disinfectant use solution concentration above 850ppm PAA	Identical
Endpoint Specification "Pass"	Solid Black > 850 ppm PA	Solid Black > 850 ppm PA	Identical
Performance	• Dynamic Range • Comparative sensitivity and specificity • Analytic Specificity	• Dynamic Range • Comparative sensitivity and specificity • Analytic Specificity	Identical
Test Strip Components	• Chromatography paper supplier • Adhesive type • Test Strip dimensions / Pad material	• Chromatography paper supplier • Adhesive type • Test Strip dimensions / Pad material	Similar
Packaging Configuration	• Aluminum vial • 50 Test Strips per vial • 2 Vials per box	• Polypropylene vial • 100 Test Strips per Vial • 2 Vials per box	Similar

Table 1. Device Comparison Table			
Feature	**Predicate Device K152394**	**Rapicide PA HLD Test Strips (Proposed device)**	**Comparison**
Direct or indirect body contact	No direct or indirect contact with patients or users	No direct or indirect contact with patients or users	Identical
Sterile	Non-Sterile	Non-Sterile	Identical
Shelf Life	18 Months	18 Months	Identical
Open Bottle Shelf Life	4 months	4 months	Identical
Biocompatibility	No patient or user contact	No patient of user contact	Identical

The Subject device is similar to the predicate device. It has the same intended use, scientific technology, and principles of operation. The subject device has the same endpoint specification, the same Minimum Recommended Concentration (MRC), and stability profile. The Subject device has a different vial package material and increased the number of strips per vial. Additionally, the Subject device has increased the strip length, modified the adhesive type, and uses a different chromatography paper supplier.

3. Description of Device

Rapicide PA High-Level Disinfectant Test Strip has the ability to measure the disinfectant use solution concentration above 850 ppm Peracetic Acid (PAA). This is the minimum recommended concentration (MRC) of PAA for Rapicide PA high-level disinfectant. If the solution is at or below MRC, the test strip pad will indicate a failure by turning dark grey, blue grey, violet grey, light grey, or white (no change in color). A passing result will be indicated by the test strip pad turning solid black after contact with solution at concentrations of 1100 ppm ± 20 ppm PAA.

4. Intended Use/Indications for Use

The RAPICIDE™ PA Test Strips are chemical indicators used after the disinfection cycle to ensure that the RAPICIDE™ PA High-Level Disinfectant solution is met the minimum recommended concentration of 850 ppm peracetic acid. The RAPICIDE PA Test Strips are designed for use by trained personnel who reprocess endoscopes and their accessories in facilities where endoscopies are performed.

5. Summary of Nonclinical Tests

The Subject Device has the same intended use and technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate device. Testing to assess and demonstrate performance of the subject device is summarized below.

Test	Conclusion
Dynamic Range	Met Acceptance Criteria
Comparative Sensitivity and Specificity	Met Acceptance Criteria
Analytic Specificity – Contaminants	Met Acceptance Criteria
Analytic Specificity – Other Germicides	Met Acceptance Criteria
Shelf Life	Met Acceptance Criteria
In-Use (Open Bottle) Stability	Met Acceptance Criteria

6. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device and is as safe, as effective and performs at least as well as the predicate device K152394, Class II (21 CFR 880.2800), product code JOJ.