June 11, 2024

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

Re: K241344
Trade/Device Name: MetriCide™ OPA Plus Solution Test Strip
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: May 13, 2024
Received: May 13, 2024

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.06.11 13:22:36 -04'00'

for: Christopher Dugard
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.

510(k) Number *(if known)*
K241344

Device Name
MetriCide™ OPA Plus Solution Test Strip

Indications for Use *(Describe)*
MetriCide OPA Plus Solution Test Strips are chemical indicators for use in determining whether the concentration of ortho-phthalaldehyde, the active ingredient in MetriCide OPA Plus Solution, is above or below the Minimum Recommended Concentration (MRC) of 0.3% established for MetriCide OPA Plus Solution.

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."

K241344
510(k) Summary
For
MetriCide™ OPA Plus Solution Test Strip

Sponsor Facility

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Manufacturing Facility

Contact: Anthony Piotrkowski
Director, Regulatory Affairs
Telephone: (440) 392-7437
Fax No: (440) 357-9198
Tony_piotrkowski@steris.com

Submission Date: May 13, 2024

1. Predicate Device

Trade Name:	Browne OPA Test Strip
Common/Usual Name:	Chemical Indicator
Classification:	Class II
Classification Name:	Physical/chemical Sterilization Process Indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K081427

2. Device Description

The MetriCide™ OPA Plus Solution Test Strip is for use with MetriCide™ OPA Plus ortho-Phthaldehyde (OPA) High Level Disinfectant (HLD) solution which contains 0.6% MetriCide™ as the active ingredient. The test strip is an OPA concentration indicator that was developed for another OPA HLD solution. The test strip consists of an impregnated paper pad attached to a polymer substrate (which serves as the handle) - the test strip is evaluated by looking at the color of the pad at the stated read time. In essence, the test strip, following immersion in the test solution for a specified time period (1 second), will change from a start color to an endpoint color in a manner that is dependent on the concentration of the active (OPA); the test strip is read at a specified time interval (90 seconds).

3. Indications for Use:

MetriCide OPA Plus Solution Test Strips are chemical indicators for use in determining whether the concentration of ortho-phthalaldehyde, the active ingredient in MetriCide OPA Plus Solution, is above or below the Minimum Recommended Concentration (MRC) of 0.3% established for MetriCide OPA Plus Solution.

4. Technological Characteristics

There have been no physical modifications to the subject device K241344 compared to the predicated device K081427. The mechanism of action and endpoint are the same and when exposed to the defined processing conditions, the proposed and predicate devices the same visible color change.

Note that the predicate for K081427 was K991709 where K081427 had no physical modifications from K991709; and K081427 was submitted and cleared to support a 60 second read time for K081427 compared to the 90 second read time for K991709.

Table 1 Comparison of CI Physical Description and Technological Properties

Feature	Proposed: MetriCide™ OPA Plus Solution Test Strip	Predicate: Browne OPA Test Strip (K081427)	Comparison
Intended Use / Indications for Use	MetriCide OPA Plus Solution Test Strips are chemical indicators for use in determining whether the concentration of ortho-phthalaldehyde, the active ingredient in MetriCide OPA Plus Solution, is above or below the Minimum Recommended Concentration (MRC) of 0.3% established for MetriCide OPA Plus Solution.	The Browne OPA Test Strip is a concentration monitor for use in ortho-phthalaldehyde containing germicide solutions with a minimum effective concentration of 0.3%. The Browne OPA Test Strip is dedicated for use with CidexTM OPA solution	Similar - both products monitor OPA at an MEC or MRC of 0.3%
Dip and Read Time	1 second, 90 seconds	1 second, 60 seconds	Similar
Device Design - components	Absorbent paper impregnated with indicator solution affixed to inert polypropylene film	Absorbent paper impregnated with indicator solution affixed to inert polypropylene film	Identical
Shelf Life	11 months	10 months	Similar
Color change	Light blue to purple	Light blue to purple	Identical

The only changes to the subject device K241344 compared to the predicate device K081427 are the indication for use in another brand of OPA and the consequent labeling changes, and the difference in read times. Since the 90 second read time was established for the same physical product in K991709, and the testing to support subject device K241344 was performed with a 90 second read time, the 90 second read time is acceptable for the subject device. Although the indications are changing, the intended use, to monitor OPA at an MEC or MRC of 0.3%, remains the same.

5. Performance Testing

Performance testing was completed using well established methods, i.e. those used to verify the predicate design.

Table 2. Verification Results Summary

Testing	Acceptance Criteria	Study Result
Performance Characterization	- Minimum 80% PASS results for strips tested with 0.45% MetriCide™ OPA Plus solution - 0% PASS results for strips tested with 0.3% MetriCide™ OPA Plus solution	**Pass – All criteria met**
Shelf Life		**Pass – All criteria met**
Analytic Specificity	0% PASS results for strips exposed to tap water	**Pass – Criterion met**
Contaminants Testing	0% PASS results for strips tested with contaminated 0.3% Metricide™ OPA solutions.	**Pass – Criterion met**

The results of the performed testing demonstrate that the MetriCide™ OPA Plus Solution Test Strip performs as intended.

6. Conclusion

The conclusion drawn from the non-clinical testing demonstrates that the subject device, MetriCide™ OPA Plus Solution Test Strip, is as safe, as effective, and performs as well as the legally marketed predicate device, Browne OPA Test Strip, cleared under K081427.