November 17, 2017

STERIS Corporation
Jennifer Nalepka
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K172472
Trade/Device Name: Micro-MEC 1.8% Glutaraldehyde Monitor Strip
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: August 30, 2017
Received: September 1, 2017

Dear Jennifer Nalepka:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172472

Device Name

Micro-MEC 1.8% Glutaraldehyde Monitor Strip

Indications for Use *(Describe)*

The Micro-MEC 1.8% Glutaraldehyde Monitor Strip is a semi-quantitative chemical indicator for use in determining whether the concentration of glutaraldehyde, the active ingredient in the solutions listed below, is greater than the minimum effective concentration (MEC) of 1.8% glutaraldehyde established for Micro-Cide™ 28 High Level Disinfectant (Micro-Cide™ 28 HLD)

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
Micro-MEC 1.8% Glutaraldehyde Monitor Strip

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Summary Date: November 15, 2017

Premarket Notification Number: K172472

1. Device Name

Trade Name:	Micro-MEC 1.8% Glutaraldehyde Monitor Strip
Common/usual Name:	Chemical Indicator
Device Classification:	Class II
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ)

2. Predicate Device

K012335	MetriTest 1.8 Glutaraldehyde Concentration Monitor - the predicate is identical to the proposed device.

3. Description of Device

The Micro-MEC 1.8% Glutaraldehyde Monitor Strip is a chemical indicator strip consisting of an indicator pad attached to a polymer substrate which serves as a handle. The test strip has been developed to monitor the concentration of glutaraldehyde in Micro-Cide™ 28 HLD working solution. The indicator pad is impregnated with an indicator solution that changes color from yellow to purple if the concentration of the germicide exceeds the minimum effective concentration (MEC) of the solution.

The paper pad on an unused indicator strip is yellow in color. After an immersion time (dip time) of two seconds in a Micro-Cide™ 28 HLD solution, it is read at 120 seconds to verify the glutaraldehyde concentration of >1.8%. At 120 seconds the indicator strip will exhibit a stable uniform purple color if the concentration of glutaraldehyde is >2.1%. The strip will appear yellow or patchy yellow/purple if the solution has ≤1.8% glutaraldehyde, signaling to the customer that the solution must be replaced.

The glutaraldehyde concentration of the neat, unused Micro-Cide™ 28 HLD solution is 3%. To ensure an adequate margin of safety over the MEC of the germicide, the indicator was formulated to undergo a complete color change at glutaraldehyde concentrations of 2.1% in at least 80% of the tests conducted. The concentration of glutaraldehyde that will induce a color change is sufficiently higher than the MEC for the Micro-Cide™ 28 HLD solution to ensure that the indicator (test strip) will not indicate a PASS in solutions with glutaraldehyde at or below the MEC of 1.8%. However, due to the kinetics of the chemical reaction that produces the color change, a test conducted on a Micro-Cide™ 28 HLD solution

with a glutaraldehyde concentration of 1.83-2.10% may indicate a PASS or a FAIL result.

The proposed test strip is used in the same way and performs the same as the predicate device to indicate the presence of the same glutaraldehyde concentration, >1.8%.

4. Intended Use

The Micro-MEC 1.8% Glutaraldehyde Monitor Strip is a semi-quantitative chemical indicator for use in determining whether the concentration of glutaraldehyde, the active ingredient, is greater than the minimum effective concentration (MEC) of 1.8% glutaraldehyde established for Micro-Cide™ 28 High Level Disinfectant (Micro-Cide™ 28 HLD).

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are single use chemical indicator strips that monitor the MEC of glutaraldehyde-containing germicide solutions.

Table 5-1 summarizes the comparison between the proposed device, Micro-MEC 1.8% Glutaraldehyde Monitor Strip, and the predicate.

Table 5-1. Technological Comparison to Predicate

	Proposed K172472 Micro-MEC 1.8% Glutaraldehyde Monitor Strip	**Predicate K012335 MetriTest 1.8 Glutaraldehyde Concentration Monitor**	**Comparison**
Intended Use	The Micro-MEC 1.8% Glutaraldehyde Monitor Strip is a semi-quantitative chemical indicator for use in determining whether the concentration of glutaraldehyde, the active ingredient, is above or below the minimum effective concentration (MEC) of 1.8% glutaraldehyde established for Micro-Cide™ 28 High Level Disinfectant (Micro-Cide™ 28 HLD)	The MetriTest 1.8 Glutaraldehyde Concentration Monitor is a glutaraldehyde concentration monitor for use in glutaraldehyde-containing germicide solutions with an MEC of 1.8% glutaraldehyde. The MetriTest 1.8 Glutaraldehyde Concentration Monitor is dedicated for use with Metricide 28 and Metricide Plus 30 Solutions.	Both indicators monitor the concentration greater than 1.8% glutaraldehyde germicide.
Substrate	Absorbent Paper	Absorbent Paper	Same

Indicator / reaction	Colorimetric sodium sulfite pH-based reaction	Colorimetric sodium sulfite pH-based reaction	Same
Backing	Polypropylene	Polypropylene	Same
Color change	Yellow to purple	Yellow to purple	Same
Detection	Greater than 1.8% glutaraldehyde	Greater than 1.8% glutaraldehyde	Same
Viewing	Paper on front of strip	Paper on front of strip	Same
Shelf-life, unopened	Current testing supports 8 months	24 months	Target of 24 months for proposed strip
Shelf-life, opened	90 days	90 days	Same
Dip and Read Times	Dip time = 2 second Read time at 120 seconds	Dip time = 1 seconds Read time at 60 seconds	Both dip and read times optimized for each glutaraldehyde solution.

Table 5-2 summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the Micro-MEC 1.8% Glutaraldehyde Monitor Strip is substantially equivalent to the claimed predicate device when used according to its instructions for use. The product effectively determines whether or not the concentration of the use solution of Micro-Cide™ 28 HLD solution is greater than 1.8% glutaraldehyde. These studies confirm that the device's performance meets the requirements of its pre-defined acceptance criteria and intended use.

Table 5-2 Performance Test Summary

Test	Acceptance Criteria	Result
Performance	• Minimum 80% pass results when tested with 2.1% glutaraldehyde Micro-Cide™ 28 HLD solution • 100% fail results with 1.8% glutaraldehyde Micro-Cide™ 28 HLD solution	**Pass**
Specificity	Incomplete color change when exposed to tap water only	**Pass**
Contaminants	Meets performance specifications in the presence of organic and inorganic contaminants in the test solution	**Pass**
Exposure to aggressive chemicals	Meets performance specifications after exposure to aggressive chemicals.	**Pass**
Blind study testing	Meets performance specifications with inexperienced users	**Pass**
Shelf life	Meets performance specifications at each time point after storage in different environments	**Pass**
In-use (open bottle)	Meets performance specifications at each time point after storage in different environments	**Pass**
Functional stability	Meets performance specifications at each time point after storage outside bottle	**Pass**

6. Conclusion

The Micro-MEC 1.8% Glutaraldehyde Monitor Strip intended for use with Micro-Cide™ 28 HLD solution is substantially equivalent to the predicate device, MetriTest 1.8 Glutaraldehyde Concentration Monitor. Based on the nonclinical tests performed the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device, K012335, MetriTest 1.8 Glutaraldehyde Concentration Monitor (21 CFR 880.2800 (b), Product code JOJ).