July 17, 2023

STERIS Corporation
Gregory Land
Senior Regulatory Affairs Specialist
5976 Heisley Road
Mentor, Ohio 44060

Re: K230558
Trade/Device Name: Revital-Ox PAA High Level Disinfectant Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 13, 2023
Received: June 13, 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Paulo Laranjeira -S
2023.07.17 15:08:44 -04'00'

for Clarence Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230558

Device Name
Revital-Ox PAA High Level Disinfectant Chemical Indicator

Indications for Use *(Describe)*
The Revital-Ox PAA High Level Disinfectant Chemical Indicator is designed to determine whether the peracetic acid concentration in the high-level disinfection (HLD) phase of the chosen reprocessing cycle of the enspire 300 Series AER employing Peracetic Acid (Revital-Ox PAA High Level Disinfectant) is above the minimum effective concentration (MEC) of 850 mg/L.

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
Revital-Ox PAA High Level Disinfectant Chemical Indicator

STERIS Corporation
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Lead Regulatory Affairs Specialist
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Submission Date: June 13, 2023

Submission #: K230558

1. Device Name

Trade Name:	Revital-Ox PAA High Level Disinfectant Chemical Indicator
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 (K102217, as modified by K173428)

3. Device Description

Revital-Ox PAA High Level Disinfectant Chemical Indicator is a single-use chemical indicator consisting of a polypropylene strip with indicator ink printed in a patch at one end. A clear, germicide-permeable laminate is applied over the reactive patch to protect the strip from damage during handling and to prevent the ink from leaching from the substrate.

One strip is used with each Cleaning and High-Level Disinfection (HLD) and HLD only cycle by placing the strip within the enspire 300 Series Automated Endoscope Reprocessor. At the end of the cycle, if the reactive patch has turned from the starting blue color to grey/tan, it was exposed to ≥ 850 mg/L PAA min. which indicates an effective peracetic acid dose, i.e. 'Pass'.

4. Indications for Use:

The Revital-Ox PAA High Level Disinfectant Chemical Indicator is designed to determine whether the peracetic acid concentration in the high-level disinfection (HLD) phase of the chosen reprocessing cycle of the enspire™ 300 Series AER employing Peracetic Acid (Revital-Ox™ PAA High Level Disinfectant) is above the minimum effective concentration (MEC) of 850 mg/L.

5. Comparison to Legally Marketed Predicate Device:

The proposed and predicate devices are single use chemical indicators for use in monitoring peracetic acid concentration in reprocessing cycles. The differences between the proposed and predicate devices are limited to the processor the chemical indicator is used for, the peracetic acid concentration for color change, the endpoint color and shelf life. **Table 5-1** contains a comparison of the technological characteristics and specifications of the proposed Revital-Ox PAA High Level

Disinfectant Chemical Indicator and the predicate VERIFY Chemical Indicator for SYSTEM 1E Processor.

Table 5-1. Device Comparison Table

Feature	**Proposed Revital-Ox PAA High Level Disinfectant Chemical Indicator**	**Predicate VERIFY Chemical Indicator for SYSTEM 1E Processor**	**Comparison**
Intended use	The Revital-Ox PAA High Level Disinfectant Chemical Indicator is designed to determine whether the peracetic acid concentration in the high-level disinfection (HLD) phase of the chosen reprocessing cycle of the enspire™ 300 Series AER employing Peracetic Acid (Revital-Ox™ PAA High Level Disinfectant) is above the minimum effective concentration (MEC) of 850 mg/L.	The VERIFY SYSTEM 1E Chemical Indicator (SYSTEM 1E Chemical Indicator) is a peracetic acid concentration indicator for routine monitoring of the SYSTEM 1E Liquid Chemical Sterilant Processing System employing S40 Sterilant Concentrate. The unprocessed Verify® SYSTEM 1E Chemical Indicator is blue. When exposed to a concentration of >1820 ppm (mg/L) peracetic acid found in the S40 use dilution, 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 use dilution.	Similar – both are intended to detect MEC of Peracetic Acid in processors
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	Proprietary formulation	Proprietary formulation	Identical
Cycles	Used in a high level disinfection processing system employing Revital-Ox PAA High Level Disinfectant to form a use dilution concentration of ≥850 ppm (mg/L) peracetic acid and provide 3 minutes exposure at 50 – 55°C.	Used in a liquid chemical sterilant processing system employing S40 Sterilant Concentrate to form a use dilution concentration of ≥1820 ppm (mg/L) peracetic acid and provide 6 minutes exposure at 45.5 – 60°C.	Similar – both detect a minimum concentration of Peracetic acid in a processor through an indicator color change
Mechanism of action	Bleaching of proprietary active ingredient as a result of	Bleaching of proprietary active ingredient as a result of oxidation,	Identical

Feature	Proposed Revital-Ox PAA High Level Disinfectant Chemical Indicator	Predicate VERIFY Chemical Indicator for SYSTEM 1E Processor	Comparison
	oxidation, resulting in blue to grey/tan color change.	resulting in blue to beige/pink color change.	
Peracetic acid concen-tration for the endpoint color change	> 850 mg/L PAA	> 1820 mg/L PAA	Similar – the subject device detects a lower concentration of PAA
Disposable	Yes	Yes	Identical
Shelf-life	16 months	24 months	Similar – the subject device shelf-life study is ongoing and the shelf life will be extended as data becomes available
Open bottle shelf life	90 days	6 months	Similar – the subject device has a shorter open bottle shelf life

6. Performance Testing

The following table summarizes the non-clinical performance testing.

The performance of the proposed device is summarized below:

Testing	Results
Comparative Sensitivity, Comparative Specificity, Analytic Sensitivity and Analytic Specificity Study	PASS
Post-Processing Stability Study – Outside Processor	PASS
Post-Processing Stability Study – Inside Processor	PASS
Blind Reader	PASS
Effects of Contaminants	PASS
Exposure to Temperature Extremes	PASS
Shelf Life for 16 months	PASS
Open Bottle Stability for 90 days	PASS

7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the Revital-Ox PAA High Level Disinfectant Chemical Indicator is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device (K102217 as modified by K173428), Class II (CFR 880.2800), product code JOJ.