April 17, 2024

STERIS Corporation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K240032
Trade/Device Name: Celerity Chemical Indicator for enspire 3000 CLCSPS
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: January 4, 2024
Received: March 6, 2024

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 (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: 2024.04.17 17:21:46 -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.

Submission Number *(if known)*

K240032

Device Name

Celerity Chemical Indicator for enspire 3000 CLCSPS

Indications for Use *(Describe)*

The enspire 3000 Chemical Indicator is a peracetic acid concentration indicator for routine monitoring of the liquid chemical sterilization cycle of the enspire 3000 employing S40 Sterilant.

The unprocessed enspire 3000 Chemical Indicator is blue. When exposed in the enspire 3000 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 color changes from the start to the pass color. See reference colors on the bottle.

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
Celerity Chemical Indicator for enspire 3000 CLCSPS

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

Contact: Gregory Land
Lead Regulatory Affairs Specialist
Telephone: (440) 392-7424
Email: greg_land@steris.com

Submission Date: April 15, 2024

510(k) number: K240032

1. Device Name

Trade Name:	Celerity Chemical Indicator for enspire 3000 CLCSPS
Models:	LCC015
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 S40 Sterilant (K173428)

3. Device Description

The enspire 3000 Chemical Indicator is a chemical indicator strip consisting of indicator ink containing the reactive chemicals printed on one end of a polypropylene strip. The product is manufactured by application of the indicator ink by screen printing to a substrate with the indicator ink printed thereon. A clear, sterilant-permeable polyether block amide laminate is adhesively bonded to the polypropylene strip following printing of the ink, completely covering the ink.

4. Intended Use/Indications for Use:

The enspire 3000 Chemical Indicator is a peracetic acid concentration indicator for routine monitoring of the liquid chemical sterilization cycle of the enspire 3000 employing S40 Sterilant.

The unprocessed enspire 3000 Chemical Indicator is blue. When exposed in the enspire 3000 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 color changes from the start to the pass color. See reference colors on the bottle.

5. Description of Technological Characteristics

The proposed device and predicate are physically identical and monitor the same Liquid Chemical Sterilant, S40. They differ only in the Liquid Chemical Sterilant Processing Systems in which they are intended.

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** provides a side by side comparison of the proposed and predicate devices.

Table 1: Comparison Table of Proposed and Predicate Devices

Feature	**Proposed Device VERIFY Chemical Indicator for enspire CLCSPS K240032**	**Predicate Device VERIFY Chemical Indicator for S40 Sterilant K173428**	**Comparison**
Intended use	The enspire 3000 Chemical Indicator is a peracetic acid concentration indicator for routine monitoring of the liquid chemical sterilization cycle of the enspire 3000 employing S40 Sterilant. The unprocessed enspire 3000 Chemical Indicator is blue. When exposed in the enspire 3000 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 color changes from the start to the pass color. See reference colors on the bottle.	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.	Similar. Proposed device is to be used with the same sterilant at the same MEC but in a different processor

Feature	**Proposed Device VERIFY Chemical Indicator for enspire CLCSPS K240032**	**Predicate Device VERIFY Chemical Indicator for S40 Sterilant K173428**	**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
Sterilization method and cycles	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.	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.	Identical
Mechanism of action	Bleaching of lissamine green B dye as a result of oxidation, resulting in a color change.	Bleaching of lissamine green B dye as a result of oxidation, resulting in a 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	26 months;	24 months	Similar
Open bottle shelf life	6 months	6 months	Identical
Intended Processor	Enspire 3000 CLCSPS	System 1E LCSPS & System 1E Endo LCSPS	Similar
Processor Basin	10.8 L	10.8 L	Identical
Sterilant Type	Peracetic Acid	Peracetic Acid	Identical
Sterilant Source	STERIS S40 Sterilant Concentrate	STERIS S40 Sterilant Concentrate	Identical

Feature	Proposed Device VERIFY Chemical Indicator for enspire CLCSPS K240032	Predicate Device VERIFY Chemical Indicator for S40 Sterilant K173428	Comparison
S40 Nominal Dose and Concentration	67.73 mL 35 % PAA 2187 mg/L (PAA in use dilution)	67.73 mL 35 % PAA 2187 mg/L (PAA in use dilution)	Identical
S40 End of Shelf-Life Dose and Concentration	≥ 61.4 mL ≥ 31.5% PAA 2022 mg/L (PAA in use dilution)	≥ 61.4 mL ≥ 31.5% PAA 2022 mg/L (PAA in use dilution)	Identical
Exposure time	6-minutes	6-minutes	Identical

6. Performance Testing

Table 2 summarizes the non-clinical testing performed for the proposed device that has demonstrated that the product is safe and effective.

Table 2: Summary of Performance Testing

Testing	Acceptance Criteria	Results
Non-Reactive Ink Suitability Study	100% of indicator text ink shows no smearing, no discoloration and no fading	PASS
Comparative Sensitivity, Comparative Specificity, Analytic Sensitivity and Analytic Specificity Study	• A minimum of 75% of indicator from each lot to show a PASS result when exposed to Pass cycle • 100% of indicators to show a FAIL result when exposed to the Fail cycle • 100% of indicators show no delamination affecting the color change • 100% of indicators show no deformation	PASS
Post-Processing Stability (Outside Processor) Study	• A minimum of 75% of indicator from each lot to show a PASS result when exposed to Pass cycle at each time point • 100% of indicators to show a FAIL result when exposed to the Fail cycle at each time point	PASS
Post-Processing Stability (Inside Processor) Study	• A minimum of 75% of indicator from each lot to show a PASS result when exposed to Pass cycle at each time point • 100% of indicators to show a FAIL result when exposed to the Fail cycle at each time point • 100% CI from each lot correctly interpreted by inexperienced reader	PASS
Blind Study	• A minimum of 75% of indicator from each lot to show a PASS result when exposed to Pass cycle • 100% of indicators to show a FAIL result when exposed to the Fail cycle • 100% CI from each lot correctly interpreted by inexperienced reader	PASS
Contaminants Study	• 100% of indicators to show a FAIL result when exposed to the Fail cycle	PASS
Exposure to Temperature Extremes Study	• CI start color to remain unchanged after exposure to three freeze/thaw cycles before processing. • ≥75% CI from each lot to show a PASS result. • 100% of indicators to show a FAIL result when exposed to the Fail cycle.	PASS

Testing	Acceptance Criteria	Results
Light Stability Study	• CI start color to remain unchanged after exposure to fluorescent light before processing. • ≥75% of indicator from each lot to show a PASS result when exposed to Pass cycle. • 100% of indicators to show a FAIL result when exposed to the Fail cycle.	PASS
Open Bottle Stability Study	• ≥75% of indicator from each lot to show a PASS result when exposed to Pass cycle. • 100% of indicators to show a FAIL result when exposed to the Fail cycle.	PASS
Shelf Life Study	• ≥75% of indicator from each lot to show a PASS result when exposed to Pass cycle. • 100% of indicators to show a FAIL result when exposed to the Fail cycle.	PASS
Human Factors Study	• Users complete all critical tasks	PASS

Table 3: Provides a comparison of the Sensitivity and Specificity testing performed on the proposed and predicate devices.

Table 3: Sensitivity and Specificity comparison Table

	Proposed Device VERIFY Chemical Indicator for enspire CLCSPS K240032		**Predicate Device VERIFY Chemical Indicator for S40 Sterilant K173428**	
Number Lots tested	3		3	
Pass Condition	≥2200 mg/L PAA	Result: 100% PASS	Approximately 2390 mg/L PAA	Result: 100% PASS
Fail Condition	1750 – 1820 mg/L PAA	Result: 100% FAIL	1750 – 1820 mg/L PAA	Result: 100% FAIL
Fail Condition	0 mg/L PAA	Result: 100% FAIL	0 mg/L PAA	Result: 100% FAIL
Study Conclusion	The proposed device met the acceptance criteria for Comparative Sensitivity (=1.00), Comparative Specificity (=1.00), Analytic Specificity (100% FAIL) and		Comparative Sensitivity and Specificity values of 1.00 demonstrated the ability of the	

	Accuracy (100% PASS in Pass condition and 100% FAIL in Fail condition), when tested in the enspire 3000 CLCSPS (Eclipse EPS) using the S40 Sterilant Concentrate.	processed CI strip to provide reliable results. Predicate device demonstrated Analytic Specificity by exhibiting no observable color change when exposed to all components of the processor cycle except the diluted PAA concentrate solution.

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 (21 CFR 880.2800), product code JOJ.