April 4, 2025

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

Re: K243475
Trade/Device Name: Chemical Indicator for enspire CLCSPS (LCC015)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ

Dear Gregory Land:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 4, 2024. Specifically, FDA is updating this SE Letter missing signatory authority's signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Christopher Dugard, OHT4: Office of Surgical and Infection Control Devices, (240) 402-6031, christopher.dugard@fda.hhs.gov.

Sincerely,

Christopher K. Dugard
-S

Christopher K. Dugard, M.S.
Division 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Trade/Device Name: Chemical Indicator for enspire CLCSPS (LCC015)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 8, 2024
Received: November 8, 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.

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,

Christopher K. Dugard -S

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Division Director
DHT4C: Division of Infection Control Devices
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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)*

K243475

Device Name

Chemical Indicator for enspire CLCSPS (LCC015)

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.**

# 510(k) Summary
# For
# Celerity Chemical Indicator for enspire 3000 CLCSPS
# K243475

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: December 2, 2024

## 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

Celerity Chemical Indicator for enspire 3000 CLCSPS (K240032)

## 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.

**Modification for Which Clearance is Being Sought:** There were no physical changes to the device and are no new indications for use. The labeling was modified to include an additional pass reference color and a gradient between the original and new pass reference colors to improve user interpretation of chemical indicator.

## 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. Technological Characteristic Comparison

The proposed device and its predicate are physically identical and have the same Indications for Use. They differ only in the product labelling. The proposed device has additional graphics to aid the user in identifying Pass conditions.

**Table 1**

| Feature | Proposed Celerity Chemical Indicator for enspire CLCSPS | Predicate K240032 Celerity Chemical Indicator for enspire CLCSPS | 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.<br><br>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 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.<br><br>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. | Identical |
| 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 | > 1820 mg/L PAA | > 1820 mg/L PAA | Identical |

| Feature | Proposed Celerity Chemical Indicator for enspire CLCSPS | Predicate K240032 Celerity Chemical Indicator for enspire CLCSPS | Comparison |
|---|---|---|---|
| concen-tration for the endpoint color change | | | |
| Disposable | Yes | Yes | Identical |
| Shelf-life | 26 months; | 26 months | Identical |
| Open bottle shelf life | 6 months | 6 months | Identical |

## 6. Performance Testing

The following table summarizes the non-clinical testing that has demonstrated that the product is substantial equivalent to the predicate device (K240032).

| Testing | Acceptance Criteria | Results |
|---|---|---|
| Human Factors Study | • Users performed all critical tasks successfully | PASS |

## 7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K240032), Class II (CFR 880.2800), product code JOJ.