August 20, 2024

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

Re: K242189
Trade/Device Name: CELERITY HP Indicator Tape (PCC077)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: July 24, 2024
Received: July 25, 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: 2024.08.20 15:45:50 -04'00'

for: Christopher Dugard
Assistant 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

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)*

K242189

Device Name

CELERITY HP Indicator Tape (PCC077)

Indications for Use *(Describe)*

The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink/magenta) to orange, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

The tape may be used in the following sterilization cycles:
• Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible, and Specialty Cycles of the V-PRO: 1, 1 Plus, maX, maX 2, 60, and s2 Low Temperature Sterilization Systems.
• Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear

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 HP Indicator Tape (PCC077)
K242189

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: July 24, 2024

1. Predicate Device

Trade Name:	CELERITY HP Indicator Tape (PCC077)
Common/Usual Name:	Chemical Indicator
Classification:	Class II
Classification Name:	Physical/chemical Sterilization Process Indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K240760

2. Device Description

The CELERITY HP Indicator Tape (Indicator Tape) is a ¾" wide crepe paper tape printed with diagonal stripes of a vaporized hydrogen peroxide (VHP) reactive ink. The ink is sealed with a varnish, the function of which is to inhibit removal of the ink via transference or by the adhesive (as the tape is dispensed). The reactive ink meets the performance specifications for a Type 1 process indicator for vaporized hydrogen peroxide as defined in ANSI/AAMI/ISO 11140-1:2014.

3. Indications for Use:

The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink/magenta) to orange, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

The tape may be used in the following sterilization cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible, and Specialty Cycles of the V-PRO: 1, 1 Plus, maX, maX 2, 60, and s2 Low Temperature Sterilization Systems.
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear
- Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear.

4. Technological Characteristics

The proposed and predicate devices are chemical indicators in accordance with ISO 11140-1:2014 for use in monitoring Vaporized Hydrogen Peroxide sterilization cycles. The mechanism of action and endpoint are the same and when exposed to the defined processing conditions, the proposed and predicate devices exhibit a visible color change.

Table 1 Comparison of CI Physical Description and Technological Properties

Feature	Proposed: CELERITY HP Indicator Tape	Predicate: CELERITY HP Indicator Tape (K240760)	Comparison
Intended Use / Indications for Use	The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink/magenta) to orange, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches. The tape may be used in the following sterilization cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible, and Specialty Cycles of the V-PRO: 1, 1 Plus, maX, maX 2, 60, and s2 Low Temperature Sterilization Systems. • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear	The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink/magenta) to orange, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches. The tape may be used in the following sterilization cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible, and Specialty Cycles of the V-PRO: 1, 1 Plus, maX, maX 2, 60, and s2 Low Temperature Sterilization Systems. • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear	Identical
Chemical Indicator Agent and Performance Specification	The indicator agent is a vaporized hydrogen peroxide reactive ink that meets the requirement specified in ANSI/AAMI/ISO 11140-1:2014 for a Type 1 Process Indicator for a vaporized hydrogen peroxide process	The indicator agent is a vaporized hydrogen peroxide reactive ink that meets the requirement specified in ANSI/AAMI/ISO 11140-1:2014 for a Type 1 Process Indicator for a vaporized hydrogen peroxide process	Identical
Device Design	Tape: 3/4" wide by 60 yards long crepe (masking) tape which is wound around a 3" core. A hydrogen peroxide reactive ink is laid down on the non-adhesive surface. The ink is protected from transfer to the adhesive via a coating.	Tape: 3/4" wide by 60 yards long crepe (masking) tape which is wound around a 3" core. A hydrogen peroxide reactive ink is laid down on the non-adhesive surface. The ink is protected from transfer to the adhesive via a coating.	Identical
Shelf Life	5 months – real-time testing is ongoing	5 months – real-time testing is ongoing	Identical
Performance Limitations	Do not overlap the tape onto itself as this may prevent the underlying layer from being appropriately exposed to hydrogen peroxide resulting in a failed indicator response.	Do not overlap the tape onto itself as this may prevent the underlying layer from being exposed to hydrogen peroxide resulting in a failed indicator response.	Identical

5. Performance Testing

No testing was required to verify the labeling change. The revised labeling is in accordance with recommendations in "User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry" April 1, 2003.

6. 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 (K240760, Class II as per 21 CFR 880.2800, product code JOJ).