October 27, 2023

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

Re: K233187
Trade/Device Name: Celerity Vaporized VH2O2 Process Indicator Adhesive Label (PCC078)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 28, 2023
Received: September 28, 2023

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233187

Device Name

Celerity Vaporized VH2O2 Process Indicator Adhesive Label (PCC078)

Indications for Use *(Describe)*

The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack has been exposed to the:

• Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization System, or

• Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For K233187
Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (PCC078)

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Tony Piotrkowski
Director, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 357-9198
e-mail: Tony_Piotrkowski@steris.com

Summary Date: October 17, 2023

Premarket Notification Number: K233187

1. Device Name

Trade Name:	Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label
Device Class:	Class II
Common/usual Name:	Chemical Indicator
Classification Name:	Physical/chemical process indicator
Classification Number:	21 CFR 880.2800
Product Code:	JOJ

2. Predicate Device

K192020 Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label

Table 1. Device Comparison Table for Modified Label and Predicate

Feature	Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (Predicate Device/K192020)	Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (Modified Device)	Comparison
Intended Use / Indications for Use	The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack has been exposed to the: • Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or • Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack has been exposed to the: • Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization System, or • Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	Added indication for use in the Specialty Cycle which is the subject of this submission
Device design - components	Indicator Ink printed onto spun-bonded polyolefin with an adhesive and a glassine backing	Indicator Ink printed onto spun-bonded polyolefin with an adhesive and a glassine backing	Same
Indicator agent	Non-transferable indicator ink of proprietary formulation which changes color when exposed to VH2O2	Non-transferable indicator ink of proprietary formulation which changes color when exposed to VH2O2	Same
Sterilization method and cycles	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60, V-PRO maX 2, V-PRO s 2 Low Temperature Sterilizers and ASP STERRAD 100S, NX and 100NX System, including those systems with ALLClear Technology.	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60, V-PRO maX 2, V-PRO s 2 Low Temperature Sterilizers and ASP STERRAD 100S, NX and 100NX System, including those systems with ALLClear Technology.	Same
Endpoint specifications	No Endpoint Specifications (Type 1 Process Indicator)	No Endpoint Specifications (Type 1 Process Indicator)	Same
Endpoint stability	15 months	15 months	Same

Feature	Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (Predicate Device/K192020)	Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (Modified Device)	Comparison
Recommended storage conditions	5–25°C/41-77°F, away from direct light. Do not store indicator labels near heat, moisture, oxidizing agents, acids/alkalis or cleaning/disinfecting agents.	5–25°C/41-77°F, away from direct light. Do not store indicator labels near heat, moisture, oxidizing agents, acids/alkalis or cleaning/disinfecting agents.	Same
Specification	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a VH2O2 Type 1 Process Indicator	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a VH2O2 Type 1 Process Indicator	Same

3. Reference Device

K231490 VERIFY V24 Self-Contained Biological Indicator (SCBI)

4. Description of Device

The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (PI) is to be affixed to the outside of a pack by means of the adhesive back. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen Fast or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

5. Intended Use/Indications for Use

The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

6. Summary of Nonclinical Tests

Testing was submitted as part of K231490 to demonstrate that the VERIFY V24 Self-Contained Biological Indicator (SCBI) label remained adhered to the vial and had appropriate color change in the Specialty Cycle and this testing is also applicable to the Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label for the following reasons:

- The subject device has the same indicator ink as the reference vial indicator label of the VERIFY V24 SCBI

- The subject device has the same substrate as the reference vial indicator label of the VERIFY V24 SCBI
- The subject device has the same adhesive as the reference vial indicator label of the VERIFY V24 SCBI
- The subject device is used to monitor the same cycle (Specialty) as the reference vial indicator label of the VERIFY V24 SCBI
- The subject device is cleared for use in the V-PRO maX 2 Fast Non Lumen Cycle which has identical preconditioning and exposure phases to the Specialty Cycle.
- The subject device is adhered to plastic of a pouch and the reference vial indicator label of the VERIFY V24 SCBI adheres to the plastic SCBI vial.

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 well as the legally marketed predicate device K192020, Class II (21 CFR 880.2800), product code JOJ.