January 7, 2022

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

Re: K213262
Trade/Device Name: CELERITY HP Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: QKM
Dated: December 7, 2021
Received: December 8, 2021

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 (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,

Clarence W. Murray, III, PhD
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)*
K213262

Device Name
Celerity™ HP Chemical Indicator

Indications for Use *(Describe)*
The Celerity™ HP Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles:

- 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.

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 Chemical Indicator (CI)

Sponsor Facility

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Manufacturing Facility

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Tony_piotrkowski@steris.com

Submission Date: January 6, 2022

510K number: K213262

1. Predicate Device

Trade Name:	3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E
Common/Usual Name:	Chemical Indicator Classification: Class II
Classification Name:	Physical/chemical sterilization processindicator
510(k) Submitter/Holder:	3M Corporation
510(k) Number:	K203284

2. Device Description

The Celerity™ HP Chemical Indicator is a chemical indicator strip consisting of indicator ink containing the reactive chemicals printed on one end of a polypropylene strip. If the critical variables are achieved, the color of the indicator ink changes from magenta to orange/yellow or lighter yellow when exposed to the V-PRO® Low Temperature Sterilization System cycles or ASP STERRAD® System cycles. The indicator is validated to function as a multiple variable indicator with increased resistance characteristics similar to ISO 11140-1:2014 end points for a Type 4 Vaporized Hydrogen Peroxide (VHP) Chemical Indicator (CI). No changes have been made to the device other than additional testing and updating the labeling for multivariable indicator claims.

3. Indications for Use

The Celerity™ HP Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles:

- 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.

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 similar and when exposed to the defined processing conditions, the proposed and predicate devices exhibit a visible color change.

Table 4-1. Summary of CI Physical Description and Technological Properties

Feature	Proposed: Celerity™ HP Chemical Indicator	Predicate: K203284, 3M Attest Tri-Metric Chemical Indicator	Comparison
Intended Use / Indications for Use	The Celerity™ HP Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles: • 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.	Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following hydrogen peroxide sterilization sterilizers and cycles: STERRAD® 100S System, STERRAD® NX® System (Standard and Advanced cycles), STERRAD® NX® System with AllClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX® System (Standard, Flex, Express and Duo cycles) STERRAD® 100NX® System with AllClear™ Technology (Standard, Flex, Express and Duo cycles) vaporized hydrogen peroxide sterilizers and STERIS® V-PRO® 1 (Lumen cycle), STERIS® V-PRO® 1 Plus (Lumen and Non-Lumen cycles) and STERIS® V-PRO® maX Low Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® 60 Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-lumen cycles), STERIS® V- PRO® s2 Low Temperature Sterilization System (Lumen, Non- Lumen, Flexible, and Fast cycles)	Both predicate and subject indicators are used for monitoring the same STERRAD and V-PRO sterilization cycles.
Device design	Indicator Ink printed onto polypropylene.	The 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E is a chemical indicator consisting of a non-cellulose based coated indicator strip sensitive to vaporized hydrogen peroxide, contained in a film laminate	Both proposed and predicate devices have a VH2O2 reactive ink on a non-cellulosic substrate that demonstrates a color change when exposed to VH2O2.
Indicator agent	Proprietary	Proprietary	Both proposed and predicate devices have a VH2O2 reactive ink that demonstrates a color change when exposed to VH2O2.
Critical parameters	4.7 mg/L - VH2O2 29 second - exposure time 50 °C – exposure Temperature	5.1 mg/L - VH2O2 1 minute - exposure time 50 °C – exposure Temperature	Both proposed and predicate devices only react when all the variables are reached.
Color change	Magenta to orange/yellow or lighter yellow	Blue to pink with a moving dye front	Both proposed and predicate devices use color changes that are the same as other cleared devices.
Endpoint stability	15 months	At least one month (4 weeks)	Both proposed and predicate devices include labeling to indicate endpoint stability.

The predicate and proposed devices are similar in terms of basic scientific technology and indications for use. Testing is included in the submission to demonstrate that the proposed CI meets the criteria of a multivariable indicator and to extend the endpoint color stability. The multivariable indicator claims change the product code from JOJ to QKM. Both product codes are under regulation number 21 CFR 880.2800.

5. Performance Testing

Performance testing was conducted to verify that the proposed Celerity CI meets the requirements for multivariable chemical indicator using the Type 4 vaporized hydrogen peroxide sterilization indicator requirements defined in ANSI/AAMI/ISO 11140-1:2014. In addition, ongoing endpoint color stability testing has demonstrated stability throughout 15 months, so the labeling has been updated to reflect this.

Table 5-1. Verification Results Summary

Testing	Purpose	Acceptance Criteria	Study Result
Multivariable CI Performance Testing	Demonstrates that the indicator reacts to all critical variables (time, temperature and sterilant concentration) of the sterilization process.	Pass testing per Table 8 of ISO 11140-1:2014	**Pass.** All CI show a complete color change
		Fail testing per Table 8 of ISO 11140-1:2014	**Pass.** All CI show an incomplete color change
Endpoint color stability	Demonstrates that the processed indicator color does not significantly change over the labeled time period.	Color remains stable	**Pass.** Color stable up to 15 months
Simulated Use Testing (Leveraged from K192020)	Demonstrates that the indicator performs as expected in a commercial sterilizer with worst-case load.	Complete color change in a full cycle. Incomplete color change in an abbreviated cycle.	**Pass.** Complete color change in a full cycle. Incomplete color change in an abbreviated cycle.

The results of the performed testing demonstrate that the Celerity™ HP Chemical Indicator performs as intended.

6. Conclusion

The conclusion drawn from the non-clinical test demonstrate that the subject device is as safe, as effective and perform as well as or better that the legally marketed predicate device (K203284, Class II as per 21 CFR 880.2800, product code QKM).