December 10, 2018

STERIS Corporation
Eileen McCafferty
Senior Regulatory Affairs Specialist
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K182724
Trade/Device Name: Celerity™ 10 STEAM Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 27, 2018
Received: September 28, 2018

Dear Eileen McCafferty:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182724

Device Name
Celerity™ 10 STEAM Chemical Indicator

Indications for Use *(Describe)*
The Celerity 10 STEAM Chemical Indicator is intended for use in dynamic air removal steam sterilization cycles operating at 270°F/132°C for 10 minutes. The Celerity 10 STEAM Chemical Indicator is a Type 6 indicator that changes colors from yellow to blue/purple when exposed to these cycle conditions.

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 K182724
Celerity™ 10 STEAM Chemical Indicator

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Submission Date: September 27, 2018

1. Device Name

Trade Name:	Celerity™ 10 STEAM Chemical Indicator
Models:	PCC058
Common Name:	Chemical Indicator.
Classification Name:	Physical/chemical sterilization process indicator
Classification	21 CFR 880.2800(b)
Product Code	JOJ

2. Predicate Device

STERIS VERIFY 270F 4 Indicator (K070461)

3. Device Description

The Celerity 10 STEAM Chemical Indicators are Type 6 emulating indicators. Type 6 indicators are cycle verification indicators which are designed to react to all critical variables for specific sterilization cycles.

They are designed to be placed in the center of each pack (e.g. tray, protective case, approved rigid sterilization container) to be sterilized and change color from yellow to blue/purple when the critical sterilization parameters have been met (270°F /132°C for 10 minutes).

They shall be printed onto white polypropylene with a polypropylene laminate and dimensions of 140 x 22 mm.

4. Indications for Use:

The Celerity 10 STEAM Chemical Indicator is intended for use in dynamic air removal steam sterilization cycles operating at 270°F/132°C for 10 minutes. The Celerity 10 STEAM Chemical Indicator is a Type 6 indicator that changes colors from yellow to blue/purple when exposed to these cycle conditions.

5. Technological Characteristic Comparison Table

A comparison of technical characteristics is summarized in **Table 5-1.**

Table 5-1. Device comparison table.

Feature	Proposed Celerity 10 STEAM Chemical Indicator	Predicate K070461 STERIS VERIFY 270F 4 Indicator	Comparison
Intended use	The Celerity 10 STEAM Chemical Indicator is intended for use in dynamic air removal steam sterilization cycles operating at 270°F/132°C for 10 minutes. The Celerity 10 STEAM Chemical Indicator is a Type 6 indicator that changes colors from yellow to blue/purple when exposed to these cycle conditions.	The VERIFY® Steam Indicators are chemical indicators intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The indicators change color from yellow to blue/purple when exposed to the proper time and temperature of the designated steam sterilization cycle. The performance of the VERIFY® Steam Indicators exceeds that of biological indicator kill and meets the requirements of ANSI/AAMI / ISO 11140-1:2005 for Class 6 steam indicators.	Both devices have the same color changes when exposed to the proper steam sterilization cycle, however the proposed device has a new indication for use in a dynamic air removal steam sterilization cycle at 270°F/132°C for 10 minutes. Wording has been updated for the proposed device from Class 6 to Type 6 to match the ANSI/AAMI/ISO 11140-1:2014 revision.
Device design -components	Printed indicator ink onto white polypropylene with a polypropylene laminate and dimensions of 140 x 22 mm.	Printed indicator ink onto white polypropylene with a polypropylene laminate and dimensions of 143 x 22 mm.	Identical except for a minor dimension difference of 3 mm in length.
Indicator agent	Proprietary pH sensitive indicator ink	Proprietary pH sensitive indicator ink	Identical
Sterilization method and cycles	Dynamic air removal STEAM sterilization	Dynamic air removal STEAM sterilization	Identical
Mechanism of action	Chemical pH dependent	Chemical pH dependent	Identical
Endpoint Specifications (Stated Value)	270°F (132°C) / 10 minutes	270°F / 4 minutes	The proposed device is designed for a 10 minute cycle rather than 4 minutes.

Feature	Proposed Celerity 10 STEAM Chemical Indicator	Predicate K070461 STERIS VERIFY 270F 4 Indicator	Comparison
Disposable	Yes	Yes	Identical
Shelf-life	3 years	3 years	Identical

6. Summary of Non-Clinical Performance Testing

Performance testing was conducted to verify that the proposed indicator meets the requirements for Type 6 emulating indicators as defined in ANSI/AAMI ISO 11140-1:2014 and additional FDA requirements using a resistometer conforming to ANSI/AAMI ISO 18472. Additional testing was completed to simulate typical in-use applications and to verify shelf life and the endpoint color stability. **Table 5-2** summarizes this non-clinical testing.

Table 5-2. Performance Testing Summary Table

Testing	Acceptance Criteria	Conclusion
ISO 11140-1 Testing	Meet requirements defined in ANSI/AAMI/ISO 11140-1:2014 along with additional FDA requirements for Type 6 emulating indicators	**PASS**
Simulated Use Testing	Demonstrate color change when exposed to a full cycle and no/incomplete color change when exposed to an abbreviated cycle	**PASS**
Shelf Life for 36 months	Meet performance specifications at each time point after storage in different environments	**PASS**
Endpoint Color Stability for 12 months	Meet performance specifications at each time point after storage in typical conditions	**PASS**

7. Conclusion

The Celerity 10 STEAM Chemical Indicator has met the established performance criteria. 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 (K070461), Class II (CFR 880.2800), product code JOJ.