



February 21, 2018

STERIS Corporation
Anthony Piotrkowski
5976 Heisley Rd
Mentor, Ohio 44060

Re: K173629

Trade/Device Name: CELERITY 20 Steam Process Challenge Device for Gravity Cycles
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 22, 2017
Received: November 24, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,


Michael J. Ryan -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

Indications for Use

510(k) Number (if known)

K173629

Device Name

CELERITY 20 Steam Process Challenge Device for Gravity Cycles

The Celerity 20 Steam Challenge Pack is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers.

The validated steam sterilization cycles include:

- 250°F (121°C) 30-minute gravity
- 270°F (132°C) 15-minute gravity

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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STERIS®



**510(k) Summary
For
CELERITY 20 Steam Process Challenge Device for Gravity
Cycles**

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Submission Date: January 23, 2018

Premarket Notification Number: K173629

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

K173629 STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Celerity 20 Steam Process Challenge Device for Gravity Cycles

1. Device Name

Trade Name: CELERITY 20 Steam Process Challenge Device for Gravity Cycles

Common/usual Name: Biological Indicator Pack (PCD)

Device Classification: Class II

Classification Name: Sterilization Process Indicator
(21 CFR 880.2800, FRC)

2. Predicate Device

VERIFY Assert STEAM Process Challenge Device for Gravity Cycles, K170070

3. Description of Device

Celerity 20 Steam Process Challenge Device for Gravity Cycles (PCD), contains a Celerity 20 Steam Biological Indicator (SCBI) and a steam chemical integrator, sealed within a plastic tray with foil cover. The tray has a molded channel which serves as the tortuous pathway for air removal/steam penetration during steam sterilization. The PCD is designed and validated to be equivalent to the standard 16-towel test pack described in ANSI/AAMI ST79. The proposed and predicate are identical except for the BI in the PCD.

4. Intended Use/ Indications for Use

The Celerity 20 Steam Challenge Pack is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers.

The validated steam sterilization cycles include:

- 250°F (121°C) 30-minute gravity
- 270°F (132°C) 15-minute gravity

5. Summary of Technical Characteristics

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

K173629 STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Celerity 20 Steam Process Challenge Device for Gravity Cycles

Table 5-1. Summary of PCD Physical Description and Technological Properties

| Feature | Celerity Gravity PCD (K173629) Proposed | Assert Gravity PCD (K170070) Predicate | Comparison |
|---|---|---|---|
| Intended Use | <p>The Celerity 20 Steam Challenge Pack is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers. The validated steam sterilization cycles include:</p> <ul style="list-style-type: none"> • 250°F (121°C) 30-minute gravity • 270°F (132°C) 15-minute gravity | <p>The VERIFY™ ASSERT™ STEAM Process Challenge Device for Gravity Cycles is used for qualification, routine microbial monitoring, and cycle monitoring of steam sterilizers. The validated steam sterilization cycles include:</p> <ul style="list-style-type: none"> • 250°F (121°C) 30-minute gravity • 270°F (132°C) 15-minute gravity <p>The VERIFY Assert Self-Contained Indicator within the Process challenge device must be used with the VERIFY Incubator for Assert Self Contained Biological Indicators. When used in conjunction with the VERIFY Incubator for Assert Self Contained Biological Indicators, the VERIFY Assert Self-Contained Indicator within the Process challenge device provides a fluorescent result within 40 minutes.</p> | Both are intended for monitoring steam sterilization cycles. |
| General Design | Indicators are sealed in plastic tray with channel to limit steam penetration/air removal. | Indicators are sealed in plastic tray with channel to limit steam penetration/air removal. | The PCD housing is identical for the two devices |
| Biological Indicator | Celerity 20 Steam Biological Indicator (20-minute fluorescent result) | Verify Assert Self Contained Biological Indicator (40-minute fluorescent result) | Both contain 510(k) Biological Indicators with rapid fluorescent results. |
| Chemical Integrator | Chemical Integrator | Chemical Integrator | Both contain the same chemical integrator |
| Means to distinguish processed PCD from unprocessed | Proposed device's internal integrator is visible through the pack. | Proposed device's internal integrator is visible through the pack. | Same |

K173629 STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Celerity 20 Steam Process Challenge Device for Gravity Cycles

Any differences between the predicate and proposed device are addressed through the testing described in Section 18 of this submission.

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-2** below.

Table 5-2. Summary of Non-clinical Testing

| Test | Acceptance Criteria | Conclusion |
|----------------------------------|--|-------------------|
| Simulated Use | <ul style="list-style-type: none">• Performance of the BI in the PCD is equivalent to the performance of the BI in the AAMI reference pack in their respective sterilization processes | PASS |
| | <ul style="list-style-type: none">• Performance of the chemical integrator in the PCD is equivalent to the performance of the chemical integrator in AAMI reference pack in their respective processes | PASS |
| | <ul style="list-style-type: none">• PCD provides an equivalent or greater challenge than the AAMI standardized test pack | PASS |
| BI in pack vs BI outside of pack | PCD provides a greater challenge to the process than the BI itself. | PASS |
| CI in pack vs CI outside of pack | PCD provides a greater challenge to the process than the integrator by itself. | PASS |
| Chemical Integrator | Chemical integrator does not reach endpoint before BI is inactivated. | PASS |

7. Conclusion

The Celerity 20 Steam Process Challenge Device for Gravity Cycles has met the established performance criteria. The results of the studies demonstrate that the biological indicator performs as intended, and based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as the legally marketed predicate device, VERIFY Assert STEAM Process Challenge Device for Gravity Cycles, cleared in K170070 (21 CFR 880.2800, Product code FRC).