February 21, 2018

STERIS Corporation
Anthony Piotrkowski
Senior Manager, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K173626
Trade/Device Name: Celerity 20 Steam Process Challenge Device for Dynamic Air Removal 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

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)*
K173626

Device Name
CELERITY 20 Steam Process Challenge Device for Dynamic Air Removal Cycles

Indications for Use ***(Describe)***
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:

- 270°F (132°C) 4-minute dynamic air removal (Prevac, SFPP)
- 275°F (135°C) 3-minute dynamic air removal (Prevac, SFPP)

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 20 Steam Process Challenge Device for Dynamic Air Removal Cycles

Sponsor Facility

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

Manufacturing Facility

STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax No: (440) 392-7896

Contact: Anthony Piotrkowski
Senior Manager Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 639-6258
e-mail: tony_piotrkowski@steris.com

Submission Date: January 23, 2018

Premarket Notification Number: K173626

1. Device Name

Trade Name:	Celerity 20 Steam Process Challenge Device for Dynamic Air Removal 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

3M Attest Super Rapid 5 Steam-Plus Challenge Pack K121593

Reference Device: Verify Assert Steam Process Challenge Device, K162945

3. Description of Device

The Celerity 20 Steam Process Challenge Device for Dynamic Air Removal Cycles (PCD), contains a Celerity 20 Steam Biological Indicator (BI) and a VERIFY Steam Integrating Indicator – Short, 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.

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:

- 270°F (132°C) 4-minute dynamic air removal (Prevac, SFPP)
- 275°F (135°C) 3-minute dynamic air removal (Prevac, SFPP)

5. Summary of Technical Characteristics

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

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

Feature	Celerity PCD (K173626) Proposed	Attest 41482V (K121593) Predicate	Comparison
Intended Use	The Celerity 20 STEAM Process Challenge Device is used for qualification, routine microbial monitoring, and load monitoring of steam sterilizers. The validated steam sterilization cycles include: • 270F (132°C), 4-minute dynamic air removal; (Prevac, SFPP) • 275F(135°C), 3-minnute dynamic air removal; (Prevac, SFPP)	Use 3M Attest Super Rapid 5 Steam-Plus Challenge Pack in conjunction with the 3M Attest Auto-reader 490 to qualify or monitor dynamic air removal (prevacuum) steam sterilization cycles of 4 minutes at 270 F (132 C) and 3 minutes at 275 F (135 C). The 3M Attest Super Rapid Readout Biological Indicator contained within the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.	Both are intended for monitoring 270F (132C), 4-minute dynamic air removal 275F(135C), 3-minnute dynamic air removal, steam sterilization cycles.
General Design	Indicators are sealed in plastic tray with channel to limit steam penetration/air removal.	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Both the devices are contained in a steam barrier. Simulated use testing demonstrated equivalence
Biological Indicator	Celerity 20 Steam Biological Indicator (20-minute fluorescent result)	Attest 1492V Biological Indicator (1-hour fluorescent result)	Both contain 510(k)-cleared Biological Indicators with rapid fluorescent results.
Chemical Integrator	VERIFY STEAM Integrating Indicator-Short	SteriGage Chemical Integrator	Both contains 510(k)-cleared chemical integrators
Means to distinguish processed PCD from unprocessed	Proposed device's internal integrator is visible through the pack.	External process indicator.Yellow to brown color change when exposed to steam	Both have a means to distinguish processed PCD from unprocessed

The Celerity 20 Steam Process Challenge Device for Dynamic Air Removal Cycles is identical to the reference device VERIFY Assert Steam Process Challenge Device except for the biological indicator within the device. The difference in the biological indicator allows the Celerity BI to have a 20-minute read (versus 40-minutes for the reference device). The different BI also requires a different reader.

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	• 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 • 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 • PCD provides an equivalent or greater challenge than the AAMI standardized test pack	PASS PASS 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

7. Conclusion

The Celerity 20 Steam Process Challenge Device for Dynamic Air Removal Cycles has met the established performance criteria. The results of the studies performed 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 at least as safely and effectively as the legally marketed predicate devices, Class II (21 CFR 880.2800, Product code FRC).