September 24, 2025

STERIS Corporation
Logan Persons
Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K252680
Trade/Device Name: Celerity™ 20 HP Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: August 25, 2025
Received: August 25, 2025

Dear Logan Persons:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen A. Anisko -S

Stephen A. Anisko -S
2025.09.24 13:53:17
-04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252680

Device Name
Celerity™ 20 HP Biological Indicator

Indications for Use *(Describe)*

The Celerity™ 20 HP Biological Indicator (Bl) is intended for routine monitoring of the following sterilizer cycles:

• Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible and Specialty Cycles of the V-PRO 1, 1 Plus, maX, maX 2, 60 and s2 Low Temperature Sterilization Systems.
• STERRAD® 100S Sterilizer (Default Cycle)
• Standard and Advanced Cycles of the STERRAD® NX® Sterilizer with or without ALLClear
• Standard, FLEX, Express and DUO Cycles of the STERRAD® 100NX® Sterilizer with or without ALLClear® Technology

When used in conjunction with the Celerity™ HP Incubator or the Celerity™ Incubator, the Celerity™ 20 HP Bl provides a fluorescent result within 20 minutes.

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 (K252680)
For
Celerity™ 20 HP Biological Indicator

Sponsor Facility
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax: (440) 357-9198

Manufacturing Facility
STERIS Corporation
9325 Pinecone Drive
Mentor, OH 44060
Phone: (440) 392-7800
Fax: (440) 392-7896

Contact
Logan Persons
Regulatory Affairs Specialist
Phone: (440) 514-4504
Fax: (440) 357-9198
Email: Logan_Persons@steris.com

Submission Date:
September 17, 2025

STERIS®

1. Device Name

Trade Name:	Celerity™ 20 HP Biological Indicator
Common/usual Name:	Biological Indicator
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

2. Predicate Device

Proprietary Name	Celerity™ 20 HP Biological Indicator
Common/usual Name	Biological indicator
Classification Name:	Indicator, Biological Sterilization Process
510(k) Submitter/Holder	STERIS Corporation
510(k) Number:	K231490

3. Description of Device

The product is intended to monitor the vapor phased hydrogen peroxide sterilization cycles described in the indications for use. It produces an optical change (signal) that is detected by the STERIS proprietary reader, STERIS Celerity™ Incubator, within 20 minutes to confirm the viability of the biological indicator at the end of a sterilization process. The product consists of Geobacillus stearothermophilus spores and a defined nutrient media in a plastic vial. A reporter enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.

4. Intended Use/Indications for Use

The Celerity™ 20 HP Biological indicator is intended for the routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible and Specialty Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s2 Low Temperature Sterilization Systems.
- STERRAD® 100S Sterilizer (Default Cycle)
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear Technology
- Standard, FLEX, Express, and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear Technology

When used in conjunction with the Celerity™ HP Incubator or the Celerity™ Incubator, the Celerity™ HP BI provides a fluorescent result within 20 minutes.

5. Summary of Technical Characteristics

Table 1. Subject Device Comparison to the Predicate Device

Feature	Celerity™ 20 HP Biological Indicator (K252680)	Celerity™ 20 HP Biological Indicator (K231490)	Comparison
Intended Use	The Celerity™ 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible and Specialty Cycles of the V-PRO 1, 1 Plus, maX, maX 2, 60 and s2 Low Temperature Sterilization Systems. • STERRAD® 100S Sterilizer (Default Cycle) • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear Technology • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear Technology When used in conjunction with the Celerity™ HP Incubator or the Celerity™ Incubator, the Celerity™ 20 HP BI provides a fluorescent result within 20 minutes.	The Celerity™ 20 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast, Flexible and Specialty Cycles of the V-PRO 1, 1 Plus, maX, maX 2, 60 and s2 Low Temperature Sterilization Systems. • STERRAD® 100S Sterilizer (Default Cycle) • Standard and Advanced Cycles of the STERRAD® NX Sterilizer with or without ALLClear Technology • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear Technology When used in conjunction with the Celerity™ HP Incubator or the Celerity™ Incubator, the Celerity™ 20 HP BI provides a fluorescent result within 20 minutes.	Same
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same
Mechanism of action	An enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.	An enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety.	Same
Accessories	Automated incubator / reader	Automated incubator / reader	Same
Viable spore population	1.0 – 4.0 x 10^6 spore/BI	1.0 – 4.0 x 10^6 spore/BI	Same
Resistance	Resistance @ 9.1 mg/L H_2O_2: • D-value ≥ 6 sec • Kill Time ≤ 7 min Resistance @ 3.5 mg/L H_2O_2: • Survival Time ≥ 4 sec	Resistance @9.1 mg/L H_2O_2: • D-value ≥ 6 sec • Survival Time ≥ 4 sec • Kill Time ≤ 7 min	Similar. All Survive resistance lowered to 3.5 mg/L H_2O_2

Feature	Celerity™ 20 HP Biological Indicator (K252680)	Celerity™ 20 HP Biological Indicator (K231490)	Comparison
Culture Conditions	55- 59°C, media included in BI, 20-minute incubation time.	55- 59°C, media included in BI, 20-minute incubation time.	Same
Primary Packaging	Direct inoculum on plastic vial, cap with recovery media.	Direct inoculum on plastic vial, cap with recovery media.	Same
Process indicator	Celerity™ HP Indicator (K231488); magenta to yellow color change.	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	Similar. Process indicator was rebranded in K231488
Shelf-life	10 months	10 months	Same

6. Summary of Non-clinical Tests

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in Table 2.

Table 2. Performance Testing

Test	Acceptance Criteria	Result
All Survive Testing	All samples will survive a 4 second exposure	PASS
Comparative dose response to the biological model	The BI must show equivalent or greater resistance to the sterilization cycle (a greater percentage of BI growing after exposure) than the biological model. 0.8g injection weight sterilization cycle vs 0.3g injection weight biological model	PASS

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K231490), Class II (21 CFR 880.2800), product code FRC.