



April 8, 2026

STERIS Corporation
Logan Persons
Regulatory Affairs Specialist
5960 Heisley Road
Mentor, OH 44060

Re: K260766

Trade/Device Name: Celerity 5 HP Biological Indicator (LCB052)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: March 3, 2026
Received: March 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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. Digitally signed by
ANISKO -S STEPHEN A. ANISKO -S
Date: 2026.04.08
09:52:08 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection
Control Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K260766

Device Name
Celerity 5 HP Biological Indicator (LCB052)

Indications for Use (Describe)

The Celerity 5 HP Biological indicator is intended for the routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 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, the Celerity HP BI provides a fluorescent result within 5 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.

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K260766
510(k) Summary
For
Celerity 5 HP Biological Indicator (LCB052)

Sponsor Facility

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Fax: (440) 357-9198

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Contact

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

Submission Date:

March 9, 2026



1. Device Name

Trade Name: Celerity 5 HP Biological Indicator (LCB052)
 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 5 HP Biological Indicator
 Common/usual Name: Biological indicator
 Classification Name: Indicator, Biological Sterilization Process
 510(k) Submitter/Holder: STERIS Corporation
 510(k) Number: K223717

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 5 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 5 HP Biological indicator is intended for the routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible 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, the Celerity HP BI provides a fluorescent result within 5 minutes.

5. Summary of Technical Characteristics

Table 1. Subject Device Comparison to the Predicate Device



Feature	Celerity 5 HP Biological Indicator (proposed)	Celerity 5 HP Biological Indicator (K223717)	Comparison
Intended Use	<p>The Celerity 5 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles:</p> <ul style="list-style-type: none"> • Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 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 <p>When used in conjunction with the Celerity Incubator, the Celerity 5 HP BI provides a fluorescent result within 5 minutes.</p>	<p>The Celerity 5 HP Biological Indicator is intended for routine monitoring of the following sterilizer cycles:</p> <ul style="list-style-type: none"> • Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX2 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 <p>When used in conjunction with the Celerity Incubator, the Celerity 5 HP BI provides a fluorescent result within 5 minutes.</p>	Same
Indicator organism	<i>Geobacillus stearothermophilus</i>	<i>Geobacillus stearothermophilus</i>	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	<p>Resistance @ 9.1 mg/L H₂O₂:</p> <ul style="list-style-type: none"> • <u>D-value</u> ≥ 6 sec • <u>Kill Time</u> ≤ 6 min <p>Resistance @ 3.5 mg/L H₂O₂:</p> <ul style="list-style-type: none"> • <u>Survival Time</u> ≥ 4 sec 	<p>Resistance @9.1 mg/L H₂O₂:</p> <ul style="list-style-type: none"> • <u>D-value</u> ≥ 6 sec • <u>Kill Time</u> ≤ 6 min • <u>Survival Time</u> ≥ 4 sec 	Similar. All Survive resistance lowered to 3.5 mg/L H ₂ O ₂



Feature	Celerity 5 HP Biological Indicator (proposed)	Celerity 5 HP Biological Indicator (K223717)	Comparison
Culture Conditions	55- 59°C, media included in BI, 5-minute incubation time.	55- 59°C, media included in BI, 5-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.	Celerity HP Indicator (K231488); magenta to yellow color change.	Same
Shelf-life	8 months	8 months	Same

6. Summary of Non-clinical Tests

Testing was performed to evaluate performance of the subject device as compared 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

The Celerity 5 HP Biological Indicator has met the established performance criteria. 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 (K223717), Class II (21 CFR 880.2800), product code FRC.