



February 6, 2025

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

Re: K250044

Trade/Device Name: Celerity 5 HP Biological Indicator (LCB052); Celerity 5 HP Challenge Pack (LCB059); Celerity 20 HP Biological Indicator (LCB044); Celerity 20 HP Challenge Pack (LCB045)

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization Process Indicator

Regulatory Class: Class II

Product Code: FRC

Dated: January 8, 2025

Received: January 10, 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**

Digitally signed by
Stephen A. Anisko -S
Date: 2025.02.06
17:36:11 -05'00'

for: Christopher K. Dugard
Division 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

Indications for Use

510(k) Number (if known)

K250044

Device Name

Celerity 5 HP Biological Indicator (LCB052), Celerity 5 HP Challenge Pack (LCB059),
Celerity 20 HP Biological Indicator (LCB044), Celerity 20 HP Challenge Pack (LCB045)

Indications for Use (Describe)

Celerity 5 HP Biological Indicator

The Celerity 5 HP Biological Indicator (BI) 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
- 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®.

When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.

Celerity 5 HP Challenge Pack

The Celerity 5 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The Challenge Pack is not intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the Sterilizers.

Celerity 20 HP Biological Indicator

The Celerity 20 HP Biological Indicator (BI) 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.
- 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®

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

Celerity 20 HP Challenge Pack

The Celerity 20 HP Challenge Pack is intended for qualification testing of the V-PRO® Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The challenge pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the Sterilizers.

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)

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**510(k) Summary
For
Celerity 5 HP Biological Indicator and Challenge Pack**

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) 352-7325
Fax: (440) 357-9198
Email: Logan_Persons@steris.com

Submission Date:

January 10, 2025



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]

Trade Name:	Celerity 5 HP Challenge Pack (LCB059)
Common/usual Name:	Biological Indicator Challenge Pack
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

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

3. **Description of Device**

Celerity 5 HP BI

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.

Celerity 5 HP Challenge Pack

The Celerity 5 HP Challenge Pack is used in the sterile processing department, usually by service technicians or biomedical technicians to qualify the unit following installation, relocation, malfunctions or major repairs and for routine requalification testing. It consists of a Celerity 5 HP Biological Indicator and a layer of absorptive foam within a Tyvek pouch.

4. **Intended Use/Indications for Use**

Celerity 5 HP BI



The Celerity 5 HP Biological Indicator (BI) 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
- 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®.

When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.

Celerity 5 HP Challenge Pack

The Celerity HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.

5. Summary of Technical Characteristics

Table 1. BI Subject Device Comparison to the Predicate Device (Celerity 5 HP)

Feature	Celerity 5 HP BI (proposed)	Celerity 5 HP BI Predicate (K223717)	Comparison
Intended Use	The Celerity 5 HP Biological Indicator (BI) 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, maX2, 60 and s2 Low Temperature Sterilization Systems. • Standard and Advanced Cycles of the STERRAD® NX	The Celerity 5 HP Biological Indicator (BI) is intended for 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 60 and s2 Low Temperature Sterilization Systems. • Standard Cycle of the STERRAD® 100S • Standard and Advanced Cycles of	Similar. Proposed device will add the Specialty Cycle and remove the STERRAD 100S Standard Cycle



Feature	Celerity 5 HP BI (proposed)	Celerity 5 HP BI Predicate (K223717)	Comparison
	Sterilizer with or without ALLClear Standard, FLEX, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.	the STERRAD® NX Sterilizer with or without ALLClear Standard, FLEX, Express and DUO Cycles of the STERRAD® 100NX Sterilizer with or without ALLClear When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 5 minutes.	
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	Celerity Incubator	Celerity Incubator	Same
Viable spore population	1.0 – 4.0 x 10 ⁶ spore/BI	1.0 – 4.0 x 10 ⁶ spore/BI	Same
Resistance characteristics	Resistance @ 9.1 mg/L H ₂ O ₂ : - D-value ≥ 6 sec - Survival Time ≥ 4 sec - Kill Time ≤ 6 min	Resistance @ 9.1 mg/L H ₂ O ₂ : - D-value > 6 sec - Survival Time ≥ 4 sec - Kill Time ≤ 6 min	Same
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.	Celerity HP Indicator (K231488); magenta to yellow color change.	Same
Shelf-life	3 months (with target of 24 months)	10 Months	Similar

Table 2. Challenge Pack Comparison to Predicate Device (Celerity 5 HP)



Feature	Celerity 5 HP Challenge pack Proposed	Celerity 5 HP Challenge pack (K223717) Predicate	Comparison
Intended Use / Indication for Use	The Celerity 5 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	The Celerity 5 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	Same
General Design	Sealed sterilization pouch containing BI, CI and barrier material.	Sealed sterilization pouch containing BI, CI and barrier material.	Same
Biological Indicator	Celerity 5 HP Biological Indicator	Celerity 5 HP Biological Indicator	Same
Chemical Indicator	Celerity HP Chemical Indicator	Celerity HP Chemical Indicator	Same
Means to distinguish processed pack from unprocessed	Proposed device's internal indicator is visible through the pack.	Proposed device's internal indicator is visible through the pack.	Same
Required accessories	Celerity Incubator (Subject of a concurrent submission)	Celerity Incubator (Subject of a concurrent submission)	Same

6. Summary of Non-clinical Tests

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in Table 3.

Table 3. Performance Testing

Test	Acceptance Criteria	Result
Reduced Incubation Time Testing	All BI lots will demonstrate 97% or greater positive growth results at 7 days as compared to the fluorescent result at less than or equal to 5-minutes	PASS



Simulated Use Testing	All processed Bis shall be sterile following full cycle exposure sterilizer cycles.	PASS
Bacteriostasis Testing	All BIs inoculated with 10-100 <i>Geobacillus stearothermophilus</i> spores will demonstrate growth	PASS
Cap Media Testing	All BIs will demonstrate a positive fluorescent signal in the fluorescent incubators.	PASS
Stability Testing	<u>Population</u> The mean initial population at the start of the stability study must be $1.0-4.0 \times 10^6$ CFU/BI. At each subsequent time point, the mean population shall be 50-300% of the initial mean population. <u>D-value</u> D-value between 6 and 20 seconds. <u>Survival/Kill</u> Demonstration of one all survive time and one all kill time point. <u>RIT</u> All BI lots will demonstrate 97% or greater positive growth results at 7 days as compared to the fluorescent result at less than or equal to 5 minutes. <u>Media Testing</u> All BIs will demonstrate a positive fluorescent signal in the fluorescent incubators.	PASS
Specialty Cycle	All Bis will demonstrate a positive signal and growth after exposure to a sublethal cycle and a 20 hour aeration phase.	Pass
Hold Time Testing	The hold time will be established using the longest hold time where there is no statistical or practical difference from the initial hold time (time 0).	72 Hour Hold Time Established

7. Conclusion

The Celerity 5 HP Biological Indicator and Challenge Pack have 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

STERIS®



the legally marketed predicate device (K223717), Class II (21 CFR 880.2800), product code FRC.



**510(k) Summary
For
Celerity 20 HP Biological Indicator and Challenge Pack**

Sponsor Facility

STERIS Corporation
5960 Heisley Road
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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) 352-7325
Fax: (440) 357-9198
Email: Logan_Persons@steris.com

Submission Date:

January 10, 2025



8. **Device Name**

Trade Name: Celerity 20 HP Biological Indicator (LCB044)
 Common/usual Name: Biological Indicator
 Device Classification: Class II
 Classification Name: Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

Trade Name: Celerity 20 HP Challenge Pack (LCB045)
 Common/usual Name: Biological Indicator Challenge Pack
 Device Classification: Class II
 Classification Name: Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

9. **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: K183294

Proprietary Name: Celerity 20 HP Challenge Pack
 Common/usual Name: Biological indicator Challenge Pack
 Classification Name: Indicator, Biological Sterilization Process
 510(k) Submitter/Holder: STERIS Corporation
 510(k) Number: K183294

10. **Description of Device**

Celerity 20 HP BI

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.

Celerity 20 HP Challenge Pack

The Celerity 20 HP Challenge Pack is used in the sterile processing department, usually by service technicians or biomedical technicians to qualify the unit following installation, relocation, malfunctions or major repairs and for routine requalification testing. It consists of a Celerity 5 HP Biological Indicator and a layer of absorptive foam within a Tyvek pouch.

11. **Intended Use/Indications for Use**

Celerity 20 HP BI



The Celerity 20 HP Biological Indicator (BI) 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
- 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®.

When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 20 minutes.

Celerity 20 HP Challenge Pack

The Celerity HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing.

The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included.

The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.

12. Summary of Technical Characteristics

Table 4. BI Subject Device Comparison to the Predicate Device (Celerity 20 HP)

Feature	Celerity 20 HP BI (proposed)	Celerity 20 HP BI Predicate (K183294)	Comparison
Intended Use	The Celerity 20 HP Biological Indicator (BI) 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, maX2, 60 and s2 Low Temperature	The Celerity 20 HP Biological Indicator (BI) 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, maX2, 60 and s2 Low Temperature	Similar. Proposed device will remove STERRAD 100S Standard Cycle



Feature	Celerity 20 HP BI (proposed)	Celerity 20 HP BI Predicate (K183294)	Comparison
	Sterilization Systems. - 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 When used in conjunction with the Celerity® Incubator, the Incubator provides a fluorescent result within 20 minutes.	Sterilization Systems. - Standard Cycle of the STERRAD® 100S - 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 When used in conjunction with the Celerity HP Incubator, the Celerity 20 HP BI provides a fluorescent result within 20 minutes.	
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	Celerity Incubator	Celerity Incubator	Same
Viable spore population	1.0 – 4.0 x 10 ⁶ spore/BI	1.0 – 4.0 x 10 ⁶ spore/BI	Same
Resistance characteristics	Resistance @ 9.1 mg/L H₂O₂: <u>D-value</u> ≥ 6 sec <u>Survival Time</u> ≥ 4 sec <u>Kill Time</u> ≤ 6 min	Resistance @ 9.1 mg/L H₂O₂: <u>D-value</u> > 6 sec <u>Survival Time</u> ≥ 4 sec <u>Kill Time</u> ≤ 6 min	Same



Feature	Celerity 20 HP BI (proposed)	Celerity 20 HP BI Predicate (K183294)	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.	Celerity HP Indicator (K231488); magenta to yellow color change.	Same
Shelf-life	3 months (with target of 24 months)	10 Months	Similar

Table 5. Challenge Pack Comparison to Predicate Device (Celerity 20 HP)

Feature	Celerity 20 HP Challenge pack Proposed	Celerity 20 HP Challenge pack (K183294) Predicate	Comparison
Intended Use / Indication for Use	The Celerity 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	The Celerity 20 HP Challenge Pack is intended for qualification testing of the V-PRO Low Temperature Sterilization System following installation, relocation, malfunctions or major repairs and for routine requalification testing. The Challenge Pack is placed in an otherwise empty sterilizer chamber; a hospital-defined challenge load is not included. The challenge pack is not intended for routine monitoring of the V-PRO Sterilizers. It has been tested and validated solely for use in periodic testing of the sterilizers.	Same



Feature	Celerity 20 HP Challenge pack Proposed	Celerity 20 HP Challenge pack (K183294) Predicate	Comparison
General Design	Sealed sterilization pouch containing BI, CI and barrier material.	Sealed sterilization pouch containing BI, CI and barrier material.	Same
Biological Indicator	Celerity 20 HP Biological Indicator	Celerity 20 HP Biological Indicator	Same
Chemical Indicator	Celerity HP Chemical Indicator	Celerity HP Chemical Indicator	Same
Means to distinguish processed pack from unprocessed	Proposed device's internal indicator is visible through the pack.	Proposed device's internal indicator is visible through the pack.	Same
Required accessories	Celerity Incubator (Subject of a concurrent submission)	Celerity Incubator (Subject of a concurrent submission)	Same

13. Summary of Non-clinical Tests

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in Table 6.

Table 6. Performance Testing

Test	Acceptance Criteria	Result
Reduced Incubation Time Testing	All BI lots will demonstrate 97% or greater positive growth results at 7 days as compared to the fluorescent result at less than or equal to 20 minutes	PASS
Simulated Use Testing	All processed Bis shall be sterile following full cycle exposure sterilizer cycles.	PASS
Bacteriostasis Testing	All BIs inoculated with 10-100 <i>Geobacillus stearothermophilus</i> spores will demonstrate growth	PASS
Cap Media Testing	All BIs will demonstrate a positive fluorescent signal in the fluorescent incubators.	PASS
Stability Testing	<u>Population</u> The mean initial population at the start of the stability study must be 1.0-4.0 x 10 ⁶ CFU/BI. At each subsequent	PASS



	time point, the mean population shall be 50-300% of the initial mean population. <u>D-value</u> D-value between 6 and 20 seconds. <u>Survival/Kill</u> Demonstration of one all survive time and one all kill time point. <u>RIT</u> All BI lots will demonstrate 97% or greater positive growth results at 7 days as compared to the fluorescent result at less than or equal to 20 minutes. <u>Media Testing</u> All BIs will demonstrate a positive fluorescent signal in the fluorescent incubators.	
Specialty Cycle	All Bis will demonstrate a positive signal and growth after exposure to a sublethal cycle and a 20 hour aeration phase.	Pass
Hold Time Testing	The hold time will be established using the longest hold time where there is no statistical or practical difference from the initial hold time (time 0).	72 Hour Hold Time Established

14. **Conclusion**

The Celerity 20 HP Biological Indicator and Challenge Pack have 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 (K183294), Class II (21 CFR 880.2800), product code FRC.