August 7, 2023

STERIS Corporation
Gregory Land
Senior Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K231490
Trade/Device Name: Celerity 20 HP Biological Indicator; VERIFY V24 Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: May 22, 2023
Received: May 23, 2023

Dear Gregory Land:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231490

Device Name
VERIFY V24 Self-Contained Biological Indicator

Indications for Use *(Describe)*
The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Flexible, Fast, Fast Non Lumen 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)
- STERRAD® 200 Sterilizer (Default Cycle)
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer to include sterilizers with ALLClear® Technology
- Express, Flex Scope and Standard Cycles of the STERRAD® 100NX Sterilizer to include sterilizers with ALLClear® Technology.

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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231490

Device Name
Celerity 20 HP Biological Indicator

Indications for Use *(Describe)*
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 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 HP BI 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.

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510(K) Summary
For K231490
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
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Lead Regulatory Affairs Specialist
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Fax: (440) 357-9198
Email: greg_land@steris.com

Submission Date:
May 22, 2023

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:	K183294

3 Description of Device

The product is intended to monitor the vapor phased hydrogen peroxide sterilization cycles described in the indication for use. It produces an optical change in signal that is detected by the STERIS proprietary reader, Celerity 20 HP 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 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 HP BI provides a fluorescent result within 20 minutes.

5 Summary of Technical Characteristics

5.1

Feature	CELRITY 20 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (K183294)	Comparison
Intended Use	The Celerity 20 HP Biological Indicator is intended for	The Celerity 20 HP Biological Indicator is intended for	The proposed and predicate devices are identical. The

Feature	CELRITY 20 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (K183294)	Comparison
	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.	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 • Standard, Flex Scope, 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.	Specialty Cycle is a new cycle in the V-PRO maX 2 Low Temperature Sterilizer, which has been submitted in this premarket notification.
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 • Survival Time ≥ 4 sec • Kill Time ≤ 7 min	Resistance @ 9.1 mg/L H_2O_2: • D-value ≥ 6 sec • Survival Time ≥ 4 sec • Kill Time ≤ 7 min	Same

Feature	CELRITY 20 HP Biological Indicator (proposed)	Celerity 20 HP Biological Indicator (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	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	VERIFY V-PRO Chemical Indicator (K140515); magenta to yellow color change.	Same
Shelf-life	10 months	10 months	Same

6 Summary of Non-clinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in Table 5-3 below.

Table 5-3. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
Verification of Celerity HP BI Performance after V-PRO Specialty Cycle Extended Aeration	Celerity BIs exposed to the Specialty Cycle demonstrate essentially equivalent or not significantly different resistance as compared to SCBIs exposed to the 136L V-PRO Sterilizer Fast Non Lumen Cycle	Pass
Final Process Qualification of the VPRO maX2 Sterilizer Specialty Cycle	The V-PRO maX 2 Sterilizer Specialty Cycle final process qualification was successful.	Pass

7 Conclusion

Based on the intended use, technological characteristics and the non-clinical tests performed, the subject device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, the Celerity 20 HP Biological Indicator, K183294 Class II [21 CFR 880.2800(a)], product code FRC.

510(K) Summary
For K231490
VERIFY V24 Self-Contained Biological Indicator

Sponsor Facility
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Manufacturing Facility
STERIS Corporation
9325 Pinecone Drive
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Contact
Gregory Land
Lead Regulatory Affairs Specialist
Phone: (440) 352-7424
Fax: (440) 357-9198
Email: greg_land@steris.com

Submission Date:
May 22, 2023

8 Device Name

Trade Name:	VERIFY V24 Self-Contained Biological Indicator
Common/usual Name:	Biological Indicator
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR 880.2800(a), FRC]

9 Predicate Device

Proprietary Name:	VERIFY V24 Self-Contained Biological Indicator
Common/usual Name	Biological indicator
Classification Name:	Indicator, Biological Sterilization Process
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K183300

10 Description of Device

The VERIFY V24 Self-Contained Biological Indicator (SCBI) is used by healthcare facilities to monitor the V-PRO® Low Temperature Sterilization Systems. It is designed to accompany medical devices placed in the sterilizer.

The user places the VERIFY V24 SCBI into the V-PRO® Low Temperature Sterilization System and performs a sterilization cycle. After cycle completion, the SCBI can either be immediately activated or it can be held at room temperature for a maximum of 72 hours (3 days) prior to activation.

The SCBI is activated by sealing the vial and rupturing the medium ampoule using the STERIS VERIFY SCBI HP activator. The activator automatically seals the SCBI vial and releases the growth media.

The activated SCBI is incubated at 55-60°C for ≥ 24 hours. The SCBI indicates a pass if the media remains orange and non-turbid. The SCBI indicates a failure of sterilization if the media changes from orange to yellow and/or if the media is turbid.

11 Intended Use/Indications for Use

The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizer cycles:

- Lumen, Non Lumen, Flexible, Fast, Fast Non Lumen 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)
- STERRAD® 200 Sterilizer (Default Cycle)
- Standard and Advanced Cycles of the STERRAD® NX Sterilizer to include sterilizers with ALLClear® Technology
- Express, Flex Scope and Standard Cycles of the STERRAD® 100NX Sterilizer to include sterilizers with ALLClear® Technology

12 Summary of Technical Characteristics

12.1 VERIFY V24 Self-Contained Biological Indicator

Feature	VERIFY V24 SCBI (proposed)	VERIFY V24 SCBI Predicate (K183300)	Comparison
Intended Use	The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Flexible, Fast, Fast Non Lumen and Specialty Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s2 Sterilizers • STERRAD® 100S Sterilizer (Default Cycle) • STERRAD® 200 Sterilizer (Default Cycle) • Standard and Advanced Cycles of the STERRAD® NX Sterilizer to include sterilizers with ALLClear® Technology • Express, Flex Scope and Standard Cycles of the STERRAD® 100NX Sterilizer to include sterilizers with ALLClear® technology.	The VERIFY® V24 Self-Contained Biological Indicator is intended for routine monitoring of the following sterilizer cycles: • Lumen, Non Lumen, Flexible, Fast and Fast Non Lumen Cycles of the V-PRO® 1, 1 Plus, maX, maX 2, 60 and s2 Sterilizers • STERRAD® 100S Sterilizer (Default Cycle) • STERRAD® 200 Sterilizer (Default Cycle) • Standard and Advanced Cycles of the STERRAD® NX Sterilizer to include sterilizers with ALLClear® Technology • Express, Flex Scope and Standard Cycles of the STERRAD® 100NX Sterilizer to include sterilizers with ALLClear® technology.	The proposed and predicate devices are identical. The Specialty Cycle is a new cycle in the V-PRO maX 2 Low Temperature Sterilizer, which has been submitted in this premarket notification.
Indicator organism	*Geobacillus stearothermophilus*	*Geobacillus stearothermophilus*	Same
Mechanism of action	Visual detection of growth based on media color change in the presence of surviving indicator organisms.	Visual detection of growth based on media color change in the presence of surviving indicator organisms.	Same
Accessories	VERIFY Incubator and VERIFY SCBI HP Activator (optional)	VERIFY Incubator and VERIFY SCBI HP Activator (optional)	Same
Viable spore population	2.0 – 3.4 x 10^6 spore/BI	2.0 – 3.4 x 10^6 spore/BI	Same
Resistance characteristics	Resistance @ 2.7 mg/L H_2O_2: • D-value 4.0 – 8.0 sec • Survival Time 4 - 30 sec • Kill Time ≤ 16 min	Resistance @ 2.7 mg/L H_2O_2: • D-value 4.0 – 8.0 sec • Survival Time 4 - 30 sec • Kill Time ≤ 16 min	Same
Culture Conditions	55- 60°C, media included in SCBI, 24 hour incubation time.	55- 60°C, media included in SCBI, 24 hour incubation time.	Same
Primary Packaging	Direct inoculum on plastic vial, glass ampoule with recovery media.	Direct inoculum on plastic vial, glass ampoule with recovery media.	Same
Process indicator	VERIFY V24 Self-Contained Biological Indicator Vail	VERIFY V24 Self-Contained Biological Indicator Vail	Same

Feature	VERIFY V24 SCBI (proposed)	VERIFY V24 SCBI Predicate (K183300)	Comparison
	Label; magenta to orange/yellow color change.	Label; magenta to orange/yellow color change.	
Shelf-life	15 Months	15 Months	Same

13 Summary of Non-clinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in Table 5-3 below.

Table 5-3. Summary of Non-clinical Testing

Test	Acceptance Criteria	Conclusion
Verification of V24 SCBI Performance after V-PRO Specialty Cycle Extended Aeration	SCBIs exposed to the Specialty Cycle demonstrate essentially equivalent or not significantly different resistance as compared to SCBIs exposed to the 136L V-PRO Sterilizer Fast Non Lumen Cycle	Pass
Final Process Qualification of the VPRO maX2 Sterilizer Specialty Cycle	The V-PRO maX 2 Sterilizer Specialty Cycle final process qualification was successful.	Pass

14 Conclusion

Based on the intended use, technological characteristics and the non-clinical tests performed, the subject device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, the VERIFY V24 Self-Contained Biological Indicator, K183300 Class II [21 CFR 880.2800(a)], product code FRC.