510(k) Summary
For
CELERITY HP Chemical Indicator (CI)

K183295

Sponsor Facility

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Manufacturing Facility

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Submission Date: December 21, 2018

1. Predicate Device

Trade Name:	VERIFY V-PRO Chemical Indicator
Common/Usual Name:	Chemical Indicator
Classification:	Class II
Classification Name:	Physical/chemical sterilization process indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K172746

2. Device Description

The Celerity™ HP Chemical Indicator (CI) is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when placed within packs to be sterilized, through a visible change from red to orange/yellow, when the device has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

A version of the Celerity™ HP Chemical Indicator may be utilized on the V24 Self-Contained Biological Indicator Vial Label and is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed SCBIs, whilst affixed to SCBI vials to be sterilized, through a visible change from red to orange/yellow, when the SCBI has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology

2.1 Physical Description – Design, Construction, Components

The CI is composed of the following components:

- Substrate
- Indicator Ink

The PI is composed of the following components

- Substrate
- Indicator Ink
- Adhesive
- Backing Paper

The Substrate material for the CI is polypropylene (Construction C). The substrate for the PI (Construction B) is spun-bonded polyolefin with and adhesive back and a glassine backing paper. The glassine backing paper serves as a carrier for the label and is removed prior to use of the PI.

The Indicator Ink is the same for both substrates of the CI (Construction C) and the PI (Construction B). The composition of the indicator ink is not known as it is a proprietary formulation, product code INK-PF2-RY, sold by Crosstex International, Inc. of Rush, NY.

3. Indications for Use:

The Celerity™ HP Chemical Indicator (CI) is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when placed within packs to be sterilized, through a visible change from red to orange/yellow, when the device has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP® STERRAD® System, including those systems with ALLClear Technology.

A version of the Celerity™ HP Chemical Indicator (CI) may be utilized on the V24 Self-Contained Biological Indicator Vial Label and is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed SCBIs, whilst affixed to SCBI vials to be sterilized, through a visible change from red to orange/yellow, when the SCBI has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
- Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including STERRAD NX and 100NX with ALLClear Technology.

4. Technological Characteristics

The proposed and predicate devices are Type 1 single use process indicators in accordance with ISO 11140-1:2014 for use in monitoring Vaporized Hydrogen Peroxide sterilization cycles. The ink, mechanism of action, and endpoint are the same and when exposed to the defined processing conditions, the proposed and predicate devices exhibit a visible color change from magenta to yellow.

Table 1 contains a comparison of technological characteristics and specifications of the proposed Celerity™ HP Chemical Indicator Constructions B and C to the predicate Verify® V-PRO Chemical Indicator – Version 1C and 2C.

Table 1. Device Comparison Table

Feature	K183295 Proposed Celerity™ HP Chemical Indicator (CI)	K172746 VERIFY® V-PRO Chemical Indicator Versions 1C and 2C	Comparison
Intended use	The Celerity™ HP Chemical Indicator is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when placed within packs to be sterilized, through a visible change from red to orange/yellow, when the device has been exposed to the: Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP® STERRAD® System, including those systems with ALLClear Technology. A version of the Celerity™ HP Chemical Indicator may be utilized on the V24 Self-Contained Biological Indicator Vial Label and is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed SCBIs, whilst affixed to SCBI vials to be sterilized, through a visible change from red to orange/yellow, when the SCBI has been exposed to the: Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast	The VERIFY® HPU Chemical Indicator is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units when placed within packs to be sterilized to indicate, through visible change from magenta to yellow, when the device has been exposed to the Lumen, Non-Lumen, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System. The VERIFY® Vaporized VH2O2 Process Indicator Adhesive Label is Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when affixed to packs to be sterilized, through a visible color change from magenta to yellow, when the pack has been exposed to the Lumen, Non Lumen, Flexible or Fast Non Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System.	The Intended Use has been modified in the proposed device in order to include the Fast Cycle of the V-Pro s 2 Device. Additional use in the Standard, Express, Flex Scope or Duo cycles of an ASP® STERRAD® System, including those systems with ALLClear Technology. Have been added.

Feature	K183295 Proposed Celerity™ HP Chemical Indicator (CI)	K172746 VERIFY® V-PRO Chemical Indicator Versions 1C and 2C	Comparison
	sterilization cycle of a V-PRO® Low Temperature Sterilization System, or Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including STERRAD NX and 100NX with ALLClear Technology.		
Device design - components	Indicator Ink printed onto spun-bonded polyolefin with an adhesive and a glassine backing (Construction B) and polypropylene (Construction C)	Indicator Ink printed onto spun-bonded polyolefin (Version 1C) and spun bonded polyolefin with an adhesive and a glassine backing (Version 2C)	The proposed device contains the same components as the predicate device for Construction B vs Version 2C. Construction C differs from Version 1C in the material for the substrate. The predicate is spun-bonded polyolefin and the proposed device is polypropylene.
Indicator agent	Non-transferable indicator ink of proprietary formulation which changes color when exposed to VH2O2	Non-transferable indicator ink of proprietary formulation which changes color when exposed to VH2O2	Same
Sterilization method and cycles	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60, V-PRO maX 2, V-PRO s 2 Low Temperature Sterilizers and ASP STERRAD 110S, NX and 100NX System, including those systems with ALLClear Technology.	Vaporized Hydrogen Peroxide in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60 and V-PRO max 2 Low Temperature Sterilizers	The sterilization cycles for the V-PRO s 2 and ASP STERRAD 110S, NX and 100NX Systems, including those systems with ALLClear Technology, are being added for the proposed device.
Endpoint specifications	No Endpoint Specifications (Type 1 Process Indicator)	No Endpoint Specifications (Type 1 Process Indicator)	Same

Feature	K183295 Proposed Celerity™ HP Chemical Indicator (CI)	K172746 VERIFY® V-PRO Chemical Indicator Versions 1C and 2C	Comparison
Side by side testing with biological indicators?	No	No	Same
Specification	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a Type 1 Hydrogen Peroxide Chemical Indicator	Conforms to ANSI/AAMI/ISO 11140-1:2005 requirements for a Class 1 Hydrogen Peroxide Chemical Indicator	Proposed device conforms to the most recent version of the standard.

Summary

The predicate and proposed devices are identical with regards to all features except for the indications for use and materials. The differences between the proposed Celerity™ HP Chemical Indicator and the predicate device are limited to a change in the indicator ink, material in construction C and the proposed claims to include the V-PRO s 2 Low Temperature Sterilization System and associated Lumen, Non Lumen, Flexible and Fast Cycles, and the ASP® STERRAD® 110S, NX and 100NX Systems and associated Standard, Advanced, Express, Flex Scope and Duo cycles with ALLClear technology. The differences between the proposed VERIFY V24 Self-Contained Biological Indicator Vial Label and the predicate device are limited to a change in the indicator ink and the proposed claims to include the V-PRO s 2 Low Temperature Sterilization System and associated Lumen, Non Lumen, Flexible and Fast Cycles, and the ASP® STERRAD® 110S, NX and 100NX Systems and associated Standard, Advanced, Express, Flex Scope and Duo cycles with ALLClear technology.

5. Performance Testing

Performance testing was conducted to verify that the proposed VERIFY® V-PRO Chemical Indicator meets the requirements for Type 1 vaporized hydrogen peroxide sterilization indicators as defined in ANSI/AAMI/ISO 11140-1:2014. Additional testing was completed to simulate typical in-use applications.

Table 2 summarizes the verification activities that were performed, with their respective Report Name, location in the submission and result to demonstrate that the proposed Celerity™ HP Chemical Indicator is safe and effective. These studies confirm that the proposed device's performance meets the requirements of its pre-defined acceptance criteria and intended uses, and qualify the proposed device for use in the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO 60, V-PRO maX 2 and V-PRO s 2 Low Temperature Sterilization Systems and ASP STERRAD 110S, NX and 100NX Systems, including those systems with ALLClear Technology.

Table 2. Verification Results Summary

Testing	Report	Study Result
Type 1 Performance Testing	RDP186-VER1	**Pass**
Simulated Use Testing	RDP186-VAL1	**Pass**
Fluorescent Light Stability Testing	RDP186-VER2	**Pass**
Temperature Extremes Exposure (Freeze/Thaw) Testing	RDP186-VER4	**Pass**
Transference Testing	RDP186-VER3	**Pass**
Adhesion Stability (Vials) Testing	RDP186-SSL3	**Pass**
Shelf Life Testing	E120-SSL1	**Pass**
Post-Processing Stability Testing	RDP186-SSL1	**Pass**

The results of the performed testing demonstrate that the Celerity™ HP Chemical Indicator performs as intended.

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and perform at least as safely and effectively as the legally marketed predicate device (K172746, Class II (21 CFR 880.2800), product code JOJ.

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)*
K183295

Device Name
Celerity HP Chemical Indicator (CI)

Indications for Use *(Describe)*
The Celerity™ HP Chemical Indicator (CI) is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units, when placed within packs to be sterilized, through a visible change from red to orange/yellow, when the device has been exposed to the:
• Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
• Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

A version of the Celerity™ HP Chemical Indicator (CI) may be utilized on the V24 Self-Contained Biological Indicator Vial Label and is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed SCBIs, whilst affixed to SCBI vials to be sterilized, through a visible change from red to orange/yellow, when the SCBI has been exposed to the:
• Lumen, Non Lumen, Flexible, Fast Non Lumen or Fast sterilization cycle of a V-PRO® Low Temperature Sterilization System, or
• Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including STERRAD NX and 100NX 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.

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January 4, 2019

Steris Corporations
Gregory Land
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K183295
Trade/Device Name: Celerity HP Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 26, 2018
Received: November 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Elizabeth F. Claverie -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