September 5, 2019

STERIS Corporation
Gregory Land
Sr Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44077

Re: K192020
Trade/Device Name: Celerity HP Chemical Indicator, Celerity Vaporized VH2O2 Process Indicator Adhesive Label, VERIFY V24 Self-Contained Biological Indicator Vial Label
Regulation Number: 21 CFR 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: August 28, 2019
Received: August 29, 2019

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,

Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192020

Device Name
Celerity HP Chemical Indicator

Indications for Use *(Describe)*

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.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

K192020

Device Name
Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label

Indications for Use *(Describe)*

The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a 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 change from magenta to orange/yellow or lighter, when the pack 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)

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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)*

K192020

Device Name
VERIFY V24 Self-Contained Biological Indicator Vial Label

Indications for Use *(Describe)*

The VERIFY V24 Self-Contained Biological Indicator Vial Label 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)

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510(k) Summary
For
Celerity™ HP Chemical Indicator

Sponsor Facility

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Manufacturing Facility

Albert Browne Ltd., a subsidiary of STERIS Corporation
Chancery House
Rayns Way
Watermead Business Park System
Leicester LE7 1PF
United Kingdom

Contact: Gregory Land
Senior Regulatory Affairs Specialist

Telephone: (440) 392-7424
Fax No: (440) 357-9198
Greg_Land@steris.com

Submission Date: September 5, 2019

1. Predicate Device and Reference Device

1.1 Predicate Device

Trade Name:	Celerity™ HP Chemical Indicator & VERIFY V24 Self-Contained Biological Indicator Vial Label
Common/Usual Name:	Chemical Indicator
Classification:	Class II
Classification Name:	Physical/chemical sterilization process indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K183295

1.2 Reference 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 is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed units through a visible change from magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

The Celerity™ HP Chemical indicator is provided in three formats:

- Version 1: Celerity™ Chemical Indicator (CI)
- Version 2: Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (PI)
- Version 3: VERIFY V24 Self-Contained Biological Indicator Vial Label (PI)

The three formats differ in their intended location inside the load to be sterilized. Version 1 is to be placed inside a pack to be sterilized. Version 2 is to be affixed to the outside of a pack by means of the adhesive back. Version 3 is to be affixed to the outside of a Self-Contained Biological Indicator by means of the adhesive back.

Table 1 below contains information related to the different constructions and use locations of the 3 versions of the proposed device.

Version 1, 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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

Version 2, The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a 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 change from magenta to orange/yellow or lighter, when the pack 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

Version 3**,** the VERIFY® V24 Self-Contained Biological Indicator Vial Label 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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

2.1 Physical Description – Design, Construction, Components

The proposed devices are manufactured by application of the indicator ink by printing onto a substrate in a variety of shapes in three constructions:

- Construction C - Polypropylene
- Construction B - Spun-bonded polyolefin with an adhesive and a glassine backing paper

- Construction D - polypropylene with an adhesive and a glassine backing paper.

The proposed devices will consist of one of the above substrates with an indicator ink printed thereon.

Note that for Constructions B and D, the glassine backing paper serves as a carrier for the label and is removed from the VERIFY® V24 Self-Contained Biological Indicator Vial Label and Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label prior to affixing to a surface and processing.

Table 1 Correlates the three versions of the device to the constructions of substrates.

Table 1: Construction Materials and Use Locations

	Version 1: Celerity™ Chemical Indicator	Version 2: Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label	Version 3: VERIFY® V24 Self-Contained Biological Indicator Vial Label
Construction	C	B or D	B or D
Use Location	Within pack	Affixed to outside of pack	Affixed to outside of Self-Contained Biological Indicator

3. Indications for Use:

3.1 Indications for Use – Celerity™ HP Chemical Indicator

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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

3.2 Indications for Use – Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label

The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a 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 change from magenta to orange/yellow or lighter, when the pack 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

3.3 Indications for Use – VERIFY® V24 Self-Contained Biological Indicator Vial Label

The VERIFY® V24 Self-Contained Biological Indicator Vial Label 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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems 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 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 or red to orange/yellow, respectively.

Table 2 contains a comparison of technological characteristics and specifications of the proposed Celerity™ HP Chemical Indicator to Predicate 1, Celerity™ HP Chemical Indicator & VERIFY V24 Self-Contained Biological Indicator Vial Label.

Table 2. Device Comparison to Predicate 1, Celerity™ HP Chemical Indicator & VERIFY V24 Self-Contained Biological Indicator Vial Label

Feature	Proposed Celerity™ HP Chemical Indicator Constructions B, C and D	K183295 Celerity™ HP Chemical Indicator Constructions B and C	Comparison
Indications for Use – Celerity™ HP Chemical Indicator	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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	Similar

Feature	Proposed Celerity™ HP Chemical Indicator Constructions B, C and D	K183295 Celerity™ HP Chemical Indicator Constructions B and C	Comparison
Indications for Use – VERIFY® V24 Self-Contained Biological Indicator Vial Label	The V24 Self-Contained Biological Indicator Vial Label 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 magenta to orange/yellow or lighter, 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	The V24 Self-Contained Biological Indicator Vial Label 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	Similar
Indications for Use – Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label	The Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is a Type 1 vaporized hydrogen peroxide sterilization process indicator. It is designed to distinguish between processed and unprocessed packs, whilst affixed to packs to be sterilized, through a visible change from magenta to orange/yellow or lighter, when the pack 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	The V24 Self-Contained Biological Indicator Vial Label 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 or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	Similar

Feature	Proposed Celerity™ HP Chemical Indicator Constructions B, C and D	K183295 Celerity™ HP Chemical Indicator Constructions B and C	Comparison
Device design -components	Indicator Ink printed spun-bonded polyolefin with an adhesive and a glassine backing (Construction B), polypropylene (Construction C) and polypropylene substrate with an adhesive supplied and a backing paper (Construction D)	Indicator Ink printed onto spun-bonded polyolefin with an adhesive and a glassine backing (Construction B) and polypropylene (Construction C)	Similar
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 100S, 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, V-PRO maX 2, V-PRO s 2 Low Temperature Sterilizers and ASP STERRAD 100S, NX and 100NX System, including those systems with ALLClear Technology.	Same
Endpoint specifications	No Endpoint Specifications (Type 1 Process Indicator)	No Endpoint Specifications (Type 1 Process Indicator)	Same
Side by side testing with biological indicators?	No	No	Same
Specification	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a VH2O2 Type 1 Process Indicator	Conforms to ANSI/AAMI/ISO 11140-1:2014 requirements for a VH2O2 Type 1 Process Indicator	Same

Summary

The predicate and proposed devices are identical with regards to all features except for the materials. The differences between the proposed Celerity™ HP Chemical Indicator (Version 1) and the predicate Celerity™ HP Chemical Indicator (K183295, Construction C) are limited to a change in the indicator ink. The mechanism of action is the same. The starting color was amended from Red to Magenta and the endpoint when exposed to the defined processing conditions, was amended to "orange/yellow or lighter.

The differences between the proposed VERIFY V24 Self-Contained Biological Indicator Vial Label to the predicate VERIFY V24 Self-Contained Biological Indicator

Vial Label (K183295, Construction B) are limited to a change to the indicator ink and the addition of a substrate, polypropylene with an adhesive back and a glassine backing paper (Construction D). The mechanism of action is the same. The starting color was amended from Red to Magenta and the endpoint when exposed to the defined processing conditions, was amended to "orange/yellow or lighter.

Version 3 of the proposed device, the Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label is similar to the predicates VERIFY V24 Self-Contained Biological Indicator Vial Label, K183295. The differences between the proposed and the predicate device are limited to a change to the indicator ink and the addition of a substrate (Construction D); the later two changes are the subject of this submission. The mechanism of action is the same. The starting color was amended from Red to Magenta and the endpoint when exposed to the defined processing conditions, was amended to "orange/yellow or lighter.

5. Performance Testing

Performance testing was conducted to verify that the proposed Celerity™ HP 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 4 summarizes the verification activities that were performed, with their respective Report Name 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 Standard, Advanced, Express, Flex or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.

Table 4. Verification Results Summary

Testing	Methodology	Acceptance Criteria	Study Result
Type 1 Performance Testing	ANSI/AAMI/ISO 11140-1:2014	When exposed to VHP Resistometer cycles at the Fail parameters (Test Points 2 and 3): 100% Celerity™ HP Chemical Indicator stripes must show a FAIL result.	**Pass**
		When exposed to VHP Resistometer cycles at the Pass condition (Test Point 1): Minimum 90% Celerity™ HP Chemical Indicator stripes must show a PASS result.	**Pass**
Simulated Use Testing	Internal Method Used	When exposed to V-PRO maX Non Lumen 1/84 cycles with ≥50 lb load (Fail condition): 100% Celerity™ HP Chemical Indicator stripes must show a FAIL result.	**Pass**
		When exposed to V-PRO and STERRAD cycles with the worst case loads: Minimum 90% Celerity™ HP Chemical Indicator stripes must show a PASS result	**Pass**

Testing	Methodology	Acceptance Criteria	Study Result
Fluorescent Light Stability Testing	Internal Method & ANSI/AAMI/ISO 11140-1:2014	Indicator start color to remain unchanged after exposure to fluorescent lighting for ≥ 30 days before processing.	**Pass**
		When exposed to VHP Resistometer cycles at the Fail parameters following exposure to fluorescent lighting for ≥ 30 days: 100% of Indicators tested must show a FAIL results (non-visible color change or color change to another color except orange/yellow	**Pass**
		When exposed to VHP Resistometer cycles at the PASS parameters following exposure to fluorescent lighting for ≥ 30 days: Minimum 90% Indicators tested must show a PASS result (orange/yellow or lighter)	**Pass**
Temperature Extremes Exposure (Freeze/Thaw) Testing	Internal Method & ANSI/AAMI/ISO 11140-1:2014	Indicator start color to remain unchanged after exposure to extreme temperatures before processing	**Pass**

Testing	Methodology	Acceptance Criteria	Study Result
		When exposed to VHP Resistometer cycles at the Fail parameters following exposure to extreme temperatures: 100% of Indicators tested must show a FAIL results (non-visible color change or color change to another color except orange/yellow	**Pass**
		When exposed to VHP Resistometer cycles at the PASS parameters following exposure to extreme temperatures: Minimum 90% Indicators tested must show a PASS result (orange/yellow or lighter)	**Pass**
Transference Testing	ANSI/AAMI/ISO 11140-1:2014	Indicators placed between a piece of the same substrate and held together with tape, then processed in a double V-PRO maX 2 Lumen cycle (no load) and evaluated for off-set, bleed and migration.	**Pass**

Testing	Methodology	Acceptance Criteria	Study Result
		Samples with reference and text ink processed in a double V-PRO maX 2 Lumen cycle (no load) and evaluated for smearing, discoloration and fading	**Pass**
Adhesion Stability (Vials) Testing	Internal Method Used	When exposed to two consecutive V-PRO maX 2 Lumen cycles: • 0% samples show bleeding of the adhesive • 100% must be firmly affixed • 0% must show signs of peeling • Minimum 90% must show a PASS result	**Pass**
Shelf Life Testing	ANSI/AAMI/ISO 11140-1:2014	After the process indicator has been aged: Minimum of 90% of indicators must PASS Type 1 PASS conditions.	**Pass**
		After the process indicator has been aged: 100% of indicators must FAIL Type 1 FAIL conditions.	**Pass**

Testing	Methodology	Acceptance Criteria	Study Result
Post-Processing Stability Testing	Internal Method Used	Indicator processed ink color remains unchanged for a minimum of 6 months following exposure to a PASS or FAIL cycle	**Pass**

The results of the Celerity™ HP Chemical Indicator performance testing demonstrate that all three models of the device, Celerity™ HP Chemical Indicator (Construction C), V24 Self-Contained Biological Indicator Vial Label and Celerity™ Vaporized VH2O2 Process Indicator Adhesive Label (Constructions B and D), perform 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 performs as well as or better than the legally marketed predicate device (K183295, Class II, 21 CFR 880.2800, product code JOJ).