August 7, 2023

STERIS Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K231488
Trade/Device Name: Celerity™ HP Chemical Indicator; Celerity™ HP Multivariable Chemical Indicator; VERIFY HPU Chemical Indicator; VERIFY VH2O2 Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ, QKM
Dated: May 22, 2023
Received: May 23, 2023

Dear Anthony Piotrkowski:

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.

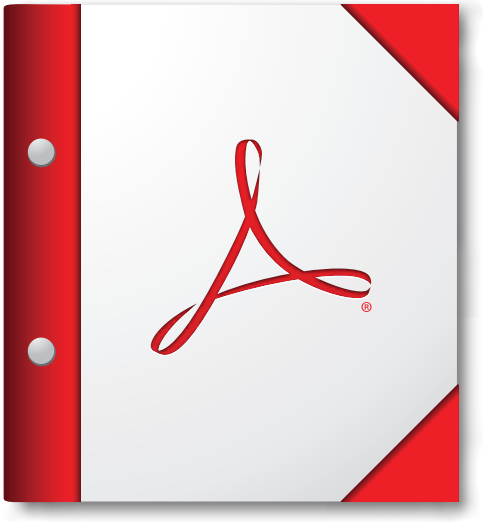
For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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



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510(k) Summary
For K231488
CELERITY HP Chemical Indicator (CI)

Sponsor Facility

STERIS Corporation
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Phone: (440) 354-2600
Fax No: (440) 639-4459

Manufacturing Facility

Albert Browne Ltd., a subsidiary of STERIS Corporation
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UNITED KINGDOM

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Tony_piotrkowski@steris.com

Submission Date: May 22, 2023

1. Predicate Device

Trade Name:	Celerity™ HP 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:	K192020

2. Device Description

The Celerity™ HP Chemical Indicator is an ISO 11140-1:2014 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. No changes have been made to the device other than additional testing and updating the labeling for the Specialty Cycle.

3. Indications for 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 or lighter, when the device has been exposed to the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty 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.

4. Technological Characteristics

The proposed and predicate devices are chemical 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 to orange/yellow or lighter yellow.

Table 4-1. Summary of CI Physical Description and Technological Properties

Feature	Proposed Celerity™ HP Chemical Indicator	Predicate: K192020 Celerity HP Chemical Indicator	Comparison
Intended Use / Indications for 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, Fast or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization	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	The Indications for Use have been modified in the proposed device in order to include the Specialty cycles.

Feature	Proposed Celerity™ HP Chemical Indicator	Predicate: K192020 Celerity HP Chemical Indicator	Comparison
	System, or Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	Standard, Advanced, Express, Flex Scope or Duo cycles of an ASP STERRAD® System, including those systems with ALLClear Technology.	
Device design – Component	Indicator Ink printed onto polypropylene (indicator) or self-adhesive polypropylene (adhesive label/vial label).	Indicator Ink printed onto polypropylene (indicator) or self-adhesive polypropylene (adhesive label/vial label).	Identical
Indicator agent	Proprietary	Proprietary	Identical
Mechanism of action	Proprietary	Proprietary	Identical
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	Identical
Color change	Magenta to orange/yellow or lighter yellow	Magenta to orange/yellow or lighter yellow	Identical
Endpoint stability	15 months (all versions)	15 months (all versions)	Identical

The predicate and proposed devices are identical with regards to all features except for the indications for use. Testing is included in the submission to demonstrate that the CI is an appropriate monitor for the V-PRO maX 2 Sterilizer Specialty cycle.

5. Performance Testing

Performance testing was completed to simulate typical in-use applications in a V-PRO maX 2 Sterilizer Specialty cycle.

Table 5-1. Verification Results Summary

Testing	Acceptance Criteria	Study Result
Simulated Use Testing	• Complete color change • No reversion	• Complete color change • No reversion

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 performs at least as safely and effectively as the legally marketed predicate device (K192020, Class II as per 21 CFR 880.2800, product code JOJ).

510(k) Summary
For K231488
CELERITY HP Multivariable Chemical Indicator (CI)

Sponsor Facility

STERIS Corporation
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Manufacturing Facility

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Submission Date: May 22, 2023

1. Predicate Device

Trade Name:	Celerity™ HP Chemical Indicator (renamed Celerity™ HP Multivariable 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:	K213262

2. Device Description

The Celerity™ HP Multivariable Chemical Indicator is a chemical indicator strip consisting of indicator ink containing the reactive chemicals printed on one end of a polypropylene strip. If the critical variables are achieved, the color of the indicator ink changes from magenta to orange/yellow or lighter yellow when exposed to the V-PRO® Low Temperature Sterilization System cycles or ASP STERRAD® System cycles. The indicator is validated to function as a multiple variable indicator with increased resistance characteristics similar to ISO 11140-1:2014 end points for a Type 4 Vaporized Hydrogen Peroxide (VHP) Chemical Indicator (CI). No changes have been made to the device other than additional testing and updating the labeling for Specialty cycle.

3. Indications for Use:

The Celerity™ HP Multivariable Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles:

- Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty 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.

4. Technological Characteristics

The proposed and predicate devices are chemical 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 to orange/yellow or lighter yellow.

Table 4-1. Summary of CI Physical Description and Technological Properties

Feature	Proposed: Celerity™ Multivariable HP Chemical Indicator	Predicate: Celerity™ HP Chemical Indicator K213262	Comparison
Intended Use / Indications for Use	The Celerity™ HP Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles: • Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast or Specialty 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.	The Celerity™ HP Chemical Indicator is a vaporized hydrogen peroxide multivariable chemical indicator. It is designed for routine monitoring of the following cycles: • 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 Intended Use of has been modified in the proposed device to include the Specialty Cycle of the V-PRO maX 2.
Device design	Proprietary Indicator Ink printed onto polypropylene.	Proprietary Indicator Ink printed onto polypropylene.	Identical
Indicator agent	Proprietary	Proprietary	Identical
Mechanism of action	Proprietary	Proprietary	Identical
Critical parameters	4.7 mg/L - VH2O2 29 second - exposure time 50 °C – exposure Temperature	4.7 mg/L - VH2O2 29 second - exposure time 50 °C – exposure Temperature	Identical
Color change	Magenta to orange/yellow or lighter yellow	Magenta to orange/yellow or lighter yellow	Identical
Endpoint stability	15 months	15 months	Identical

The predicate and proposed devices are identical with regards to all features except for the indications for use. Testing is included in the submission to demonstrate that the CI is an appropriate monitor for the V-PRO maX 2 Sterilizer Specialty cycle.

5. Performance Testing

Performance testing was completed to simulate typical in-use applications in a V-PRO maX 2 Sterilizer Specialty cycle.

Table 5-1. Verification Results Summary

Testing	Acceptance Criteria	Study Result
Simulated Use Testing	• Complete color change • No reversion	• Complete color change • No reversion

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 performs at least as safely and effectively as the legally marketed predicate device (K213262, Class II as per 21 CFR 880.2800, product code QKM).

510(k) Summary
For K231488
VERIFY HPU Chemical Indicator (CI)

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Manufacturing Facility

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Submission Date: May 22, 2023

1. Predicate Device

Trade Name:	VERIFY HPU 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 VERIFY HPU Chemical Indicator (Chemical Indicator) is a Type 1 process indicator in accordance with ANSI/AAMI/ISO 11140-1:2014. The indicators are used in the processing cycles to indicate exposure to the following sterilization cycles in the V-PRO Low Temperature Sterilization Systems. The indicator ink spot on the proposed Chemical Indicator undergoes a color change from magenta to yellow when exposed to the defined processing conditions.

3. Indications for Use:

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 a visible change from magenta to yellow, when the device has been exposed to the Lumen, Non Lumen, Flexible, Fast Non Lumen, or Specialty sterilization cycle of a V-PRO® Low Temperature Sterilization System.

4. Technological Characteristics

The proposed and predicate devices are chemical 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 to yellow.

Table 4-1. Comparison of the Proposed VERIFY HPU Chemical Indicator with the Predicate

Feature	Proposed: VERIFY HPU Chemical Indicator	Predicate: VERIFY HPU Chemical Indicator (K172746)	Comparison
Intended Use	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 a visible change from magenta to yellow, when the device has been exposed to the Lumen, Non Lumen, Flexible, Fast Non Lumen, or Specialty sterilization cycle of a	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 a visible change from magenta to yellow, when the device has been exposed to the Lumen, Non Lumen, Flexible or Fast Non	The Intended Use has been modified in the proposed device in order to include the Specialty Cycle

Feature	Proposed: VERIFY HPU Chemical Indicator	Predicate: VERIFY HPU Chemical Indicator (K172746)	Comparison
	V-PRO® Low Temperature Sterilization System	Lumen sterilization cycle of a V-PRO® Low Temperature Sterilization System	
Device design - components	Proprietary Indicator Ink printed onto spun-bonded polyolefin, (indicator) or self-adhesive spun-bonded polyolefin (indicator label).	Proprietary Indicator Ink printed onto spun-bonded polyolefin, (indicator) or self-adhesive spun-bonded polyolefin (indicator label).	Identical
Sterilization method	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide	Identical
Endpoint specifications	No Endpoint Specifications (Type 1 Process Indicator)	No Endpoint Specifications (Type 1 Process Indicator)	Identical
Shelf-life	9 months (both versions)	9 months (both versions)	Identical

The predicate and proposed devices are identical with regards to all features except for the indications for use. Testing is included in the submission to demonstrate that the CI is an appropriate monitor for the V-PRO maX 2 Sterilizer Specialty cycle.

5. Performance Testing

Performance testing was completed to simulate typical in-use applications in a V-PRO maX 2 Sterilizer Specialty cycle.

Table 5-1. Verification Results Summary

Testing	Acceptance Criteria	Study Result
Simulated Use Testing	• Complete color change • No reversion	• Complete color change • No reversion

The results of the performed testing demonstrate that the VERIFY HPU 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 performs at least as safely and effectively as the legally marketed predicate device (K172746, Class II as per 21 CFR 880.2800, product code JOJ).

510(k) Summary
For K231488
VERIFY VH2O2 Indicator Tape

Sponsor Facility

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Manufacturing Facility

Hi-Tech Products
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Submission Date: May 22, 2023

1. Predicate Device

Trade Name:	VERIFY VH2O2 Indicator Tape
Common/Usual Name:	Chemical Indicator
Classification:	Class II
Classification Name:	Physical/chemical Sterilization Process Indicator
510(k) Submitter/Holder:	STERIS Corporation
510(k) Number:	K183293

2. Device Description

The VERIFY VH2O2 Indicator Tape (Indicator Tape) is a ¾" wide crepe paper tape printed with diagonal stripes of a vaporized hydrogen peroxide (VHP) reactive ink. The ink is sealed with a varnish, the function of which is to inhibit removal of the ink via transference or by the adhesive (as the tape is dispensed). The reactive ink meets the performance specifications for a Type 1 process indicator for vaporized hydrogen peroxide as defined in ANSI/AAMI/ISO 11140-1:2014.

3. Indications for Use:

The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches.

The tape may be used in the following sterilization 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
- Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer without ALLClear.

4. Technological Characteristics

The proposed and predicate devices are chemical 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 to orange/yellow or lighter yellow.

Table 4.1 Comparison of the Proposed VERIFY VH2O2 Indicator Tape with the Predicate

Feature	Proposed: VERIFY VH2O2 Indicator Tape	Predicate: VERIFY VH2O2 Indicator Tape (K183293)	Comparison
Intended Use including Sterilization Method and Cycles	The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches. The tape may be used in the following sterilization cycles: • Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast, 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 • Standard, Flex Scope, Express and DUO Cycles of the STERRAD® 100NX Sterilizer without ALLClear	The Indicator Tape is intended to secure items wrapped in synthetic wrap materials until used and to distinguish between processed and unprocessed units through a color change from the start color (pink) to peach, yellow or lighter. The Indicator Tape is also intended to be used as an external process indicator when applied to synthetic wrap materials and/or Tyvek pouches. The tape may be used in the following sterilization cycles: • Lumen, Non Lumen, Fast Non Lumen, Fast and Flexible Cycles of the V-PRO: 1, 1 Plus, maX, maX 2 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 without ALLClear	The Intended Use of has been modified to include the Specialty Cycle of the V-PRO maX 2. Inclusion of the V-PRO 60. The Indicator Tape was cleared for use in the V-PRO 60 in K172753 but was inadvertently left off the indications in K183293
Chemical Indicator Agent and Performance Specification	The indicator agent is a vaporized hydrogen peroxide reactive ink that meets the requirement specified in ANSI/AAMI/ISO 11140-1:2014 for a Type 1 Process Indicator for a vaporized hydrogen peroxide process	The indicator agent is a vaporized hydrogen peroxide reactive ink that meets the requirement specified in ANSI/AAMI/ISO 11140-1:2014 for a Type 1 Process Indicator for a vaporized hydrogen peroxide process	Identical
End Point Specification	Tape: Pink to Peach/Yellow	Tape: Pink to Peach/Yellow	Identical
Device Design	Tape: 3/4" wide by 60 yards long crepe (masking) tape which is wound around a 3" core. A hydrogen peroxide reactive ink is laid down on the non-adhesive surface. The ink is protected from transfer to the adhesive via a coating.	Tape: 3/4" wide by 60 yards long crepe (masking) tape which is wound around a 3" core. A hydrogen peroxide reactive ink is laid down on the non-adhesive surface. The ink is protected from transfer to the adhesive via a coating.	Identical
Shelf Life	24 months	24 months	Identical
Performance Limitations (taken from instructions for use)	Do not overlap the tape onto itself as this may prevent the underlying layer from being appropriately exposed to hydrogen peroxide resulting in a failed indicator response.	Do not overlap the tape onto itself as this may prevent the underlying layer from being exposed to hydrogen peroxide resulting in a failed indicator response.	Identical

The predicate and proposed devices are identical with regards to all features except for the indications for use. Testing is included in the submission to demonstrate that the CI is an appropriate monitor for the V-PRO maX 2 Sterilizer Specialty cycle.

5. Performance Testing

Performance testing was completed to simulate typical in-use applications in a V-PRO maX 2 Sterilizer Specialty cycle.

Table 5-8. Verification Results Summary

Testing	Acceptance Criteria	Study Result
Simulated Use Testing	• Complete color change • Remain adhered after cycle	• Complete color change • Remained adhered after cycle

The results of the performed testing demonstrate that the VERIFY VH2O2 Indicator Tape 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 performs at least as safely and effectively as the legally marketed predicate device (K183293, Class II as per 21 CFR 880.2800, product code JOJ).