December 23, 2025

Shenzhen SafeSecure Medical Infection Control Tech Co. , Ltd.
Lee Parker
RA
903, Tower B, OCT Central One, Mintang Rd.
Longhua District
Shenzhen City, Guangdong 518131
China

Re: K251991
Trade/Device Name: SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016); SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator (4211, 4212, 4213)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 24, 2025
Received: November 24, 2025

Dear Lee Parker:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2025.12.23 12:31:37 -05'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251991

Device Name
SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016)

Indications for Use *(Describe)*
The SafeSecure Steam Sterilization Process Indicators are chemical process indicators intended for use by healthcare professionals to accompany individual units (e.g., wrapped packs) and to demonstrate that the unit has been exposed to a steam sterilization process.
The indicator changes color to signal exposure to sterilization conditions.
The indicators are validated for use in the following saturated steam sterilization cycles:

| Sterilization Type | Temperature | Time |
|---|---|---|
| Gravity | 250 °F/121°C | 30 minutes |
| Gravity | 270 °F/132°C | 3, 4, 10, 15, 25 minutes |
| Gravity | 275 °F/135°C | 3, 10 minutes |
| Dynamic air-removal | 250 °F/121°C | 15, 20, 30 minutes |
| Dynamic air-removal | 270 °F/132°C | 3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes |
| Dynamic air-removal | 273 °F/134°C | 3, 3.5, 4 minutes |
| Dynamic air-removal | 275 °F/135°C | 4, 10 minutes |

The product includes both label and tape indicator. The labels can be printed or written on prior to application. The tapes are designed to adhere to common sterilization wraps, including untreated woven, non-woven, paper, and paper/ plastic wraps.

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251991

Device Name
SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator (4211, 4212, 4213)

Indications for Use *(Describe)*
The SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicators are chemical process indicators intended to accompany individual packages and visually confirm that the pack has been exposed to a validated Vaporized Hydrogen Peroxide sterilization cycle.
The indicator changes color to signal exposure to sterilization conditions.
The indicators are validated for use in the following Vaporized Hydrogen Peroxide sterilization systems:
- Standard Cycle of STERRAD® 100S
- Standard cycle and Advanced cycle of STERRAD® NX
- Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX
- Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX

The product includes both label and card indicator. The labels can be printed or written on prior to application. The card is designed to be placed inside the sterilization package, next to the items being sterilized.

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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# K251991- 510(k) Summary

## 1.0 Submission Sponsor

Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.
903, Tower B, OCT Central One, Mintang Road, Longhua District,
ShenZhen City, Guangdong Province
518131 China.

Parker Lee
Tel: 86-755-27040468
Fax: 86-755-27040488
tse@anbaopack.com

## 2.0 Date Prepared

December 11, 2025

## 3.0 Device Identification

| | |
|---|---|
| Trade/Proprietary Name: | SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016)<br>SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator (4211, 4212, 4213) |
| Common/Usual Name: | Sterilization Process Indicator |
| Classification Name: | Sterilization process indicator |
| Classification Regulation: | 21 CFR 880.2800 |
| Product Code: | JOJ |
| Device Class: | 2 |
| Classification Panel: | General Hospital |

## 4.0 Predicate Device

- Steam: 3M™ Comply™ 1322 Indicator Tape (K220564)
- VHP: Terragene® Chemdye® CD42 (K191021)

## 5.0 Device Description

### 5.1 SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016)

The SafeSecure Steam Sterilization Process Indicators are Type 1 chemical process indicators compliant with ISO 11140-1:2014, designed for use in steam sterilization processes. These are external, single-use indicators intended to verify exposure to the sterilization cycle and distinguish between processed and unprocessed packs.

The product is available in two formats:

- Label-type indicators (4013, 4014): consisting of coated paper or synthetic paper backing, pressure-sensitive adhesive, chemical indicator, and a glassine release liner for easy application. 4013 allows for handwritten labeling, while 4014 features a pre-printed label format.
- Tape-type indicators (4012, 4016): composed of masking tape backing, pressure-sensitive adhesive, and a chemical indicator.

The adhesive is formulated for strong adhesion to untreated woven, non-woven, paper, and paper/plastic sterilization wraps, and allows clean removal after steam exposure.

Upon exposure to steam sterilization conditions, the indicator exhibits an irreversible color change:

- From off-white/yellow to dark brown/black (for 4012, 4013, and 4014)
- From green to gray/black (for 4016)

### 5.2 SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator(4211, 4212, 4213)

The SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicators are Type 1 chemical process indicators, compliant with ISO 11140-1:2014, designed for monitoring exposure to vaporized hydrogen peroxide sterilization cycles.

The product is available in two formats:

- Card-type indicator (4211): intended to be placed inside the sterilization package, adjacent to the medical device. It consists of a printed indicator on a plastic substrate, membrane layer, and chemical indicator agent.
- Label-type indicators (4212, 4213): intended to be affixed on the outside of the packaging. Each consists of a self-adhesive polypropylene (PP) base, glassine release liner, and an indicator agent.

The Vaporized Hydrogen Peroxide indicator undergoes a distinct, irreversible color change from red to light orange/yellow upon exposure to sterilization conditions, allowing visual confirmation of processing.

## 6.0 Indications for Use

### 6.1 SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016)

The SafeSecure Steam Sterilization Process Indicators (4012, 4013, 4014, 4016) are chemical process indicators intended for use by healthcare professionals to accompany individual units (e.g., wrapped packs) and to demonstrate that the unit has been exposed to a steam sterilization process.

The indicator changes color to signal exposure to sterilization conditions.

The indicators are validated for use in the following saturated steam sterilization cycles:

| Sterilization Type | Temperature | Time |
|---|---|---|
| Gravity | 250 °F/121°C | 30 minutes |
| Gravity | 270 °F/132°C | 3, 4, 10, 15, 25 minutes |
| Gravity | 275 °F/135°C | 3, 10 minutes |
| Dynamic air-removal | 250 °F/121°C | 15, 20, 30 minutes |
| Dynamic air-removal | 270 °F/132°C | 3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes |
| Dynamic air-removal | 273 °F/134°C | 3, 3.5, 4 minutes |
| Dynamic air-removal | 275 °F/135°C | 4, 10 minutes |

The product includes both label and tape indicator. The labels can be printed or written on prior to application.The tapes are designed to adhere to common sterilization wraps, including untreated woven, non-woven, paper, and paper/plastic wraps.

### 6.2 SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator (4211, 4212, 4213)

The SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicators (4211, 4212, 4213) are chemical process indicators intended to accompany individual packages and visually confirm that the pack has been exposed to a validated Vaporized Hydrogen Peroxide sterilization cycle.

The indicator changes color to signal exposure to sterilization conditions.

The indicators are validated for use in the following Vaporized Hydrogen Peroxide sterilization systems:

- Standard Cycle of STERRAD® 100S

- Standard cycle and Advanced cycle of STERRAD® NX
- Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX
- Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX

The product includes both label and card indicator. The labels can be printed or written on prior to application. The card is designed to be placed inside the sterilization package, next to the items being sterilized.

## 7.0 Predicate Technology Comparison

The SafeSecure Sterilization Process Indicators (Models 4012, 4013, 4014, 4016 for steam; 4211, 4212, 4213 for VHP) are classified under 21 CFR 880.2800, product code JOJ, as Class II sterilization process indicators.

The subject devices have been compared to the following predicate devices:

- 3M™ Comply™ 1322 Lead-Free Steam Indicator Tape (K220564)
- Terragene® Chemdye® CD42 Process Indicators (K191021)

The subject and predicate devices share the same intended use: to indicate exposure to steam or vaporized hydrogen peroxide sterilization processes using a visual color change.

All devices are Type 1 indicators conforming to ISO 11140-1:2014. Minor differences in color transition or shelf-life do not raise new safety or effectiveness concerns.

### 7.1 SafeSecure Steam Sterilization Process Indicator (4012, 4013, 4014, 4016)

| Item | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| **510(k) Number** | **K251991** | **K220564** | |
| **Product name** | **SafeSecure Steam Sterilization Process Indicator** | **3M™ Comply™ 1322 Lead Free Indicator Tape for Steam Sterilization** | / |
| **Manufacturer** | Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd. | 3M Health Care | / |
| **Classification** | II | II | Identical |
| **Product Code** | JOJ | JOJ | Identical |
| **Regulation Number** | 21 CFR 880.2800 | 21 CFR 880.2800 | Identical |
| **Model #** | 4012, 4013, 4014, 4016 | 1322 | / |
| **Indications for Use** | The SafeSecure Steam Sterilization Process Indicators (4012, 4013, | 3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed for | Similar[1] |

<table>
<tr><th>Item</th><th>Subject Device</th><th>Predicate Device</th><th>Comparison</th></tr>
<tr><td>510(k) Number</td><td>K251991</td><td>K220564</td><td></td></tr>
<tr><td>Product name</td><td>SafeSecure Steam Sterilization Process Indicator</td><td>3M™ Comply™ 1322 Lead Free Indicator Tape for Steam Sterilization</td><td>/</td></tr>
<tr><td></td><td>4014, 4016) are chemical process indicators intended for use by healthcare professionals to accompany individual units (e.g., wrapped packs) and to demonstrate that the unit has been exposed to a steam sterilization process. The SafeSecure Steam Sterilization Process Indicators (4012, 4013, 4014, 4016) are chemical process indicators intended for use by healthcare professionals to accompany individual units (e.g., wrapped packs) and to demonstrate that the unit has been exposed to a steam sterilization process.<br><br>The indicator changes color to signal exposure to sterilization conditions.<br><br>The indicators are validated for use in the following saturated steam sterilization cycles:
<table>
<tr><th>Sterilization Type</th><th>Temperature</th><th>Time</th></tr>
<tr><td>Gravity</td><td>250 °F/121°C</td><td>30 minutes</td></tr>
<tr><td>Gravity</td><td>270 °F/132°C</td><td>3, 4, 10, 15, 25 minutes</td></tr>
<tr><td>Gravity</td><td>275 °F/135°C</td><td>3, 10 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>250 °F/121°C</td><td>15, 20, 30 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>270 °F/132°C</td><td>3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes</td></tr>
</table></td><td>use by a health care provider to accompany individual units (e.g. wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.<br><br>Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 in steam process below:
<table>
<tr><th>Cycle Type</th><th>Temperature</th><th>Exposure Time</th></tr>
<tr><td>Gravity</td><td>250 °F /121°C</td><td>30 minutes</td></tr>
<tr><td>Gravity</td><td>270 °F /132°C</td><td>3,4, 10, 15, 25 minutes</td></tr>
<tr><td>Gravity</td><td>275 °F/ 135 °C</td><td>3, 10 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>250 °F /121°C</td><td>15, 20, 30 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>270 °F /132°C</td><td>3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>273 °F /134°C</td><td>3, 3.5, 4 minutes</td></tr>
<tr><td>Dynamic air-removal</td><td>275 °F /135°C</td><td>3,3.5,4, 10 minutes</td></tr>
</table>
Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Comply™ 1322 Lead Free Steam Indicator Tape 1322 is designed to secure packs wrapped with untreated woven and disposable non-woven paper and paper/plastic wraps.</td><td></td></tr>
</table>

| Item | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| **510(k) Number** | **K251991** | **K220564** | |
| **Product name** | **SafeSecure Steam Sterilization Process Indicator** | **3M™ Comply™ 1322 Lead Free Indicator Tape for Steam Sterilization** | / |
| | Dynamic air-removal / 273 °F/134°C / 3, 3.5, 4 minutes<br>Dynamic air-removal / 275 °F/135°C / 4, 10 minutes<br>The product includes both label and tape indicator. The labels can be printed or written on prior to application. And the tapes are designed to adhere to common sterilization wraps, including untreated woven, non-woven, paper, and paper/plastic wraps. | | |
| **Type of CI** | Type 1 Process Indicators per ISO 11140-1: 2014 | Type 1 Process Indicators per ISO 11140-1: 2014 | Identical |
| **Device Design** | The chemical indicator ink can be printed onto suitable paper substrates | The chemical indicator ink can be printed onto suitable paper substrates | Similar |
| **Indicator agent** | Proprietary | Proprietary | / |
| **Endpoint Specifications** | Color change from off-white/yellow to dark-brown/black for 4012, 4013 and 4014, or from green to gray/black for 4016 | Turns darker color when exposed to the sterilization process | Similar[2] |
| **Endpoint Stability** | 6 months | 6 months | Identical |
| **Shelf-Life** | 18 months | 18 months | Identical |

[1] The testing reports demonstrate the safety and effectiveness of device for their Indications for Use.
[2] The testing reports demonstrate the safety and effectiveness of device for their Chemical Indicator.

### 7.2 SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator(4211, 4212, 4213)

| Item | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| **510(k) Number** | **K251991** | **K191021** | |

| | | | |
|---|---|---|---|
| **Product name** | **SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator** | **Terragene® Chemdye® CD42 Process Indicators** | / |
| **Model #** | 4211, 4212, 4213 | CD42 | / |

| Item | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| **510(k) Number** | **K251991** | **K191021** | |
| **Product name** | **SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator** | **Terragene® Chemdye® CD42 Process Indicators** | / |
| **Classification** | II | II | Identical |
| **Product Code** | JOJ | JOJ | Identical |
| **Regulation Number** | 21 CFR 880.2800 | 21 CFR 880.2800 | Identical |
| **Indications for Use** | The SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicators (4211, 4212, 4213) are chemical process indicators intended to accompany individual packages and visually confirm that the pack has been exposed to a validated Vaporized Hydrogen Peroxide sterilization cycle.<br><br>The indicator changes color to signal exposure to sterilization conditions.<br><br>The indicators are validated for use in the following Vaporized Hydrogen Peroxide sterilization systems:<br><br>● Standard Cycle of STERRAD® 100S<br><br>● Standard cycle and Advanced cycle of STERRAD® NX<br><br>● Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX<br><br>● Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX<br><br>The product includes both label and card indicator. The labels can be printed or written on prior to application. The card is designed to be placed inside the sterilization package, next to the items being sterilized. | Terragene Chemdye® (CD40, CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from purple to green for CD40 and red to yellow for CD42 to indicate that the conditions of the cycle have been met.<br><br>Cycle of Vaporized Hydrogen Peroxide<br><br>STERRAD 100S 54 minutes<br><br>STERRAD Standard and Express cycles<br><br>V-Pro Max and Sterizone VP4 | Similar[1] |

| | | | |
|---|---|---|---|
| **Sterilization process** | Hydrogen Peroxide | Hydrogen Peroxide | Identical |
| **Type of CI** | Type 1 according to ISO 11140-1 | Type 1 according to ISO 11140-1 | Identical |

| Item | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| **510(k) Number** | **K251991** | **K191021** | |
| **Product name** | **SafeSecure Vaporized Hydrogen Peroxide Sterilization Process Indicator** | **Terragene® Chemdye® CD42 Process Indicators** | / |
| **Device Design** | The chemical indicator ink can be printed onto suitable paper substrates | The chemical indicator ink can be printed onto suitable paper substrates | Similar |
| **Indicator agent** | Proprietary | Proprietary | / |
| **Endpoint Specifications** | Color change from red to light orange/yellow | Color change from red to light orange/yellow | Similar[2] |
| **Endpoint Stability** | 6 months | 6 months | Identical |
| **Shelf-Life** | 18 months | 5 years | Different[2] |
| **Storage Conditions** | temperature range of 10°C-30°C (59°F-86°F) with a relative humidity range of 30%-80% | T = 10-30 °C, RH 30-80 % | Identical |

[1] The testing reports demonstrate the safety and effectiveness of device for their Indications for Use.
[2] The testing reports demonstrate the safety and effectiveness of device for their Chemical Indicator.

## 8.0 Summary of Non-Clinical Testing

The SafeSecure Sterilization Process Indicators (4012, 4013, 4014,4016) for steam, 4211, 4212,4213 for VHP) meet:

- ISO 11140-1:2014 Type 1 requirements
- FDA's 2003 Guidance for Chemical Indicators

These indicators reliably distinguish processed from unprocessed items under validated sterilization conditions.

They maintain stable performance over 18 months and demonstrate comparable endpoint performance to predicate devices. Shelf-life testing beyond 18 months is ongoing and will be updated as data become available.

| No. | Test Performed | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| 1 | Appearance | Visual | The printing is clear and does not drop, and the indicator does not change color. | Pass |
| 2 | Reaction of the critical parameters | ISO 11140-1 | Fail Condition: No Visible change<br>Successful Condition: Visible change | Pass |
| 3 | Endpoint Stability | Visual | The endpoint of the successfully sterilized sample remains stable for at least 6 months. | Pass |
| 4 | Peel Strength (If applicable) | ASTM F88/F88M | After sterilization peel strength ⩾ 1.5 N/15mm | Pass |
| 5 | Off-set | ISO 11140-1 | No offset | Pass |
| 6 | Shelf Life | Test after real-time aging | The endpoint reaction of the chemical indicator is maintained throughout its labeled shelf life. | Pass |
| 7 | Actual Sterilization Cycle Testing | Sterilization in Actual Sterilization Cycle | Fail Condition: No Visible change<br>Successful Condition: Visible change | Pass |

| No. | Test Performed | Test Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| 8 | Biocompatibility | ISO 10993-1 | Does not release any substance known to be toxic in sufficient quantities to cause a health hazard or deleterious effect to the user or the devices that are sterilized | Pass |

## 9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicates cleared under K220564 and K191021.