July 5, 2024

Advanced Sterilization Products, Inc.
Brandon Roberts
Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92618

Re: K234084

Trade/Device Name: STERRAD™ Chemical Indicator (CI) Strip (14100); STERRAD® SEALSURE® Chemical Indicator (CI) Tape (14202NL); STERRAD VELOCITY™ Biological Indicator (BI) (60 count) (43210); STERRAD VELOCITY™ Biological Indicator (BI) (30 count) (43210-30); STERRAD VELOCITY™ Reader (43220); ULTRA GI™ Process Challenge Device (PCD) Vial (30 count) (43400)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ, FRC
Dated: December 22, 2023
Received: June 7, 2024

Dear Brandon Roberts:

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.

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K234084

Device Name
STERRAD™ Chemical Indicator (CI) Strip (14100)

Indications for Use *(Describe)*

The STERRAD™ Chemical Indicator (CI) Strip is a process indicator per ISO 11140-1:2014 [Type 1] (to differentiate processed from unprocessed packages) and is intended for use with medical device packages to be sterilized in the following STERRAD™ Sterilization Systems:

- STERRAD™ 100S Sterilization System
- STERRAD NX™ Sterilization System
  - o STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology
- STERRAD™ 100NX Sterilization System
  - o STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear Technology
  - o ULTRA GI™ Cycle with Integrated ALLClear Technology

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K234084

Device Name
STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape (14202NL)

Indications for Use *(Describe)*

STERRAD™ SEALSURE™ Chemical Indicator Tape is a process indicator (ISO 11140-1:2014 [Type 1]) intended for use by health care providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD™ Sterilization Systems:

- STERRAD™ 100S Sterilization System
- STERRAD NX™ Sterilization System
    - o STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology
- STERRAD™ 100NX Sterilization System
    - o STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology
    - o ULTRA GI™ Cycle with Integrated ALLClear™ Technology

The color of the STERRAD SEALSURE Chemical Indicator Tape changes from red to gold (or lighter) indicated by comparator bar when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads.

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

510(k) Number *(if known)*
K234084

Device Name
STERRAD VELOCITY™ Biological Indicator (BI) (60 count) (43210);
STERRAD VELOCITY™ Biological Indicator (BI) (30 count) (43210-30);
STERRAD VELOCITY™ Reader (43220)

Indications for Use *(Describe)*
The STERRAD VELOCITY™ Biological Indicator (BI)/Process Challenge Device (PCD), in conjunction with the STERRAD VELOCITY™ Reader, is intended to be used as a standard method for frequent monitoring and/or periodic testing of the following STERRAD™ Systems:

- STERRAD™ 100NX Sterilization System
  - o STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology
  - o ULTRA GI™ Cycle with Integrated ALLClear Technology (for frequent monitoring only).
- STERRAD NX™ Sterilization System
  - o (STANDARD AND ADVANCED Cycles) with and without ALLClear™ Technology
- STERRAD™ 100S Sterilization System

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

510(k) Number *(if known)*
K234084

Device Name
ULTRA GI™ Process Challenge Device (PCD) Vial (43400) (30 count)

Indications for Use *(Describe)*
The ULTRA GI™ Process Challenge Device (PCD) Vial is used with the STERRAD VELOCITY™ Biological Indicator (BI) for periodic testing and frequent monitoring of the ULTRA GI™ Cycle in the STERRAD™ 100NX Sterilization System 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 K234084**
**Advanced Sterilization Products, Inc.**
**STERRAD™ Chemical Indicator (CI) Strip**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

**General Information**

Submitter Name: Advanced Sterilization Products, Inc.

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Brandon Roberts
Senior Regulatory Affairs Specialist
Phone: (323) 590-4214
Email: brandon.roberts@asp.com

Date Prepared: July 2, 2024

**Device Name**

| | |
|---|---|
| Proprietary Name: | STERRAD™ Chemical Indicator (CI) Strip (14100) |
| Common Name: | Chemical Sterilization Process Indicator Strip |
| Classification Name: | Indicator, Physical/Chemical Sterilization Process |
| Device Class: | Class II |
| Product Code: | JOJ |
| CFR Section: | 21 CFR 880.2800 |

**Predicate Device**

STERRAD® Chemical Indicator Strip cleared under 510(k) K111518 on October 3, 2012.

**Device Description**

The STERRAD™ Chemical Indicator (CI) Strip consists of chemically reactive ink, a clear overcoat ink, a yellow comparator bar, and black ink for copy printed on a strip of white styrene. This device is a through-put process indicator to be used with ASP's STERRAD™ Sterilization Systems. The STERRAD Sterilization System utilizes hydrogen peroxide gas plasma to achieve rapid, low-temperature sterilization of medical devices. When in the presence of hydrogen peroxide, the indicator will change from red to yellow as indicated by the comparator bar to indicate that the load has been exposed to hydrogen peroxide.

The STERRAD Chemical Indicator (CI) Strip does not imply that sterilization has been achieved or to assure that the sterilization cycle has been completed. Rather, it provides a visual indication that hydrogen peroxide, an essential ingredient in the operation of the STERRAD System sterilization process, is present in the sterilization chamber.

**Intended Use/Indications For Use**

The STERRAD™ Chemical Indicator (CI) Strip is a process indicator per ISO 11140-1:2014 [Type 1] (to differentiate processed from unprocessed packages) and is intended for use with medical device packages to be sterilized in the following STERRAD™ Sterilization Systems:

- STERRAD™ 100S Sterilization System
- STERRAD NX™ Sterilization System
    - STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology
- STERRAD™ 100NX Sterilization System
    - STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear Technology
    - ULTRA GI™ Cycle with Integrated ALLClear Technology

**Comparison of Technological Characteristics**

| Device Characteristics | Subject Device<br>**STERRAD™ Chemical Indicator Strip (K234084)** | Predicate Device<br>**STERRAD® Chemical Indicator Strip (K111518)** |
|---|---|---|
| **Intended Use** | The STERRAD™ Chemical Indicator (CI) Strip is a process indicator that is intended to differentiate processed from unprocessed packages and is intended for use with medical device packages to be sterilized in STERRAD™ Sterilization Systems. | Same |
| **Indications for Use** | The STERRAD™ Chemical Indicator (CI) Strip is a process indicator per ISO 11140-1:2014 [Type ] (to differentiate processed from unprocessed | The STERRAD® Chemical Indicator Strip (PN 14100) is a process indicator (ISO 11140-1:2005) to differentiate processed from unprocessed |

<table>
<tr><th rowspan="2">Device Characteristics</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><th>STERRAD™ Chemical Indicator Strip (K234084)</th><th>STERRAD® Chemical Indicator Strip (K111518)</th></tr>
<tr><td></td><td>packages) and is intended for use with medical device packages to be sterilized in the following STERRAD™ Sterilization Systems:<ul><li>STERRAD™ 100S Sterilization System</li><li>STERRAD NX™ Sterilization System<ul><li>STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology</li></ul></li><li>STERRAD™ 100NX Sterilization System<ul><li>STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear Technology</li><li>ULTRA GI™ Cycle with Integrated ALLClear Technology</li></ul></li></ul></td><td>packages and is intended for use with medical device packages to be sterilized in STERRAD® Sterilization Systems:<table><tr><th>MODEL</th><th>CYCLE</th></tr><tr><td>STERRAD® 100S</td><td>Standard</td></tr><tr><td>STERRAD® 50</td><td>Standard</td></tr><tr><td>STERRAD® 200</td><td>Standard</td></tr><tr><td rowspan="2">STERRAD® NX®</td><td>Standard</td></tr><tr><td>Advanced</td></tr><tr><td rowspan="4">STERRAD® 100NX®</td><td>Standard</td></tr><tr><td>Flex</td></tr><tr><td>Express</td></tr><tr><td>DUO</td></tr></table></td></tr>
<tr><td><u>Contraindications</u></td><td>None</td><td>Same</td></tr>
<tr><td><u>Precautions</u></td><td>1. Do not use after the expiration date.<br>2. STERRAD CI Strip is not indicated for use with steam or ethylene oxide sterilization cycles.<br>3. If the indicator bar has not completely changed from red to yellow (or lighter) indicated by the comparator bar,</td><td>Same</td></tr>
</table>

| Device Characteristics | Subject Device<br>**STERRAD™ Chemical Indicator Strip (K234084)** | Predicate Device<br>**STERRAD® Chemical Indicator Strip (K111518)** |
|---|---|---|
| | introduction of hydrogen peroxide, an essential component of the STERRAD Sterilization Cycle, may not have taken place.<br>4. Single use only. Do not reuse as the Chemical Indicator Strip will not function as intended if reused. | |
| **Regulation/Product Code** | 880.2800 /JOJ | Same |
| **Technology** | Through-put process indicator | Same |
| **Device Design: Functionality** | Strip with Chemical Indicator | Same |
| **Device Design: Chemical Reaction** | N-Oxidation of tertiary amine in the presence of hydrogen peroxide. | Same |
| **Device Design: Cycle Parameter Indication** | Hydrogen Peroxide | Same |
| **Device Design** | Indicator bar changes from red to yellow (or lighter) as indicated by comparator bar when exposed to hydrogen peroxide. | Same |
| **Distinct Color Change** | Red (pre-processed) to yellow or lighter (post-processed) as indicated by comparator bar. | Same |
| **Endpoint Color** | Yellow or lighter as indicated by comparator bar (Pantone Color Formula Guide 144C). | Same |
| **Single Use** | Yes | Same |
| **Over the Counter Use Device** | Yes | Same |
| **Packaging** | Four cartons per shipper box with each carton consisted of 250 strips placed in a polyethylene bag. | Same |

**Summary of Non-Clinical Testing**

| Performance Testing | Description | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| **Chemical Indicator Functionality** | This study verified the Chemical Indicator functionality after processing in the ULTRA GI Cycle. | The Chemical Indicator will not change color when not exposed to the cycle parameter indication.<br>The Chemical Indicator will change color when exposed to cycle parameter indication. | Pass |
| **Residual Biocompatibility** | This study demonstrated the biocompatibility of the Chemical Indicator post processing in the ULTRA GI Cycle. | The residual hydrogen peroxide level shall be below the LOQ and exhibit mild toxicity or lower. | Pass |
| **End Point /Post Processing Color Stability** | This study demonstrated that the Chemical Indicator will perform to the Type 1 requirements of ISO 11140-1:2014. | The chemical indicator shall perform to the Type 1 requirements of ISO 11140-1:2014. | Pass |

**Summary**

The subject device, STERRAD Chemical Indicator (CI) Strip (14100), and its predicate utilize the same technology and verification/validation methods to achieve its intended use. The performance testing results indicate that including the ULTRA GI Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject device to be as safe and effective as the predicate.

**Conclusion**

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the existing legally marketed predicate device, K111518.

**510(k) Summary for K234084**
**Advanced Sterilization Products, Inc.**
**STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

**General Information**

Submitter Name: Advanced Sterilization Products, Inc.

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Brandon Roberts
Senior Regulatory Affairs Specialist
Phone: (323) 590-4214
Email: brandon.roberts@asp.com

Date Prepared: July 2, 2024

**Device Name**

Proprietary Name: STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape (14202NL)
Common Name: Chemical Sterilization Process Indicator Tape
Classification Name: Indicator, Physical/Chemical Sterilization Process
Device Class: Class II
Product Code: JOJ
CFR Section: 21 CFR 880.2800

**Predicate Device**

STERRAD® SEALSURE® Chemical Indicator Tape cleared under 510(k) K111519 on October 3, 2012.

**Device Description**

The STERRAD™ SEALSURE™ Chemical Indicator Tape is a through-put process indicator tape to be used with ASP's STERRAD™ Sterilization Systems that utilize hydrogen peroxide gas plasma to achieve rapid, low-temperature sterilization of medical devices.

The Chemical Indicator Tape reacts with hydrogen peroxide as it is introduced into the sterilization chamber. The chemical reaction between the indicator ink and the hydrogen peroxide causes the dye of the indicator ink on the diagonal STERRAD logos and the chemical indicator square on the tape to change color, indicating that the load has been exposed to hydrogen peroxide.

STERRAD SEALSURE Chemical Indicator Tape does not imply that sterilization has been achieved or to assure that the sterilization cycle has been completed.

**Intended Use/Indications For Use**

STERRAD™ SEALSURE™ Chemical Indicator Tape is a process indicator (ISO 11140-1:2014 [Type 1]) intended for use by health care providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD™ Sterilization Systems:

- STERRAD™ 100S
- STERRAD NX™
    - STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology
- STERRAD™ 100NX
    - STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology
    - ULTRA GI™ Cycle with Integrated ALLClear™ Technology

The color of the STERRAD SEALSURE Chemical Indicator Tape changes from red to gold (or lighter) indicated by comparator bar when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads.

**Comparison of Technological Characteristics**

| Device Characteristics | Subject Device | Predicate Device |
|---|---|---|
| | **STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape (K234084)** | **STERRAD® SEALSURE® Chemical Indicator Tape (K111519)** |
| **Intended Use** | STERRAD SEALSURE Chemical Indicator (CI) Tape is a process indicator intended for use by healthcare providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD Sterilization Systems. | Same |

<table>
<tr><th rowspan="2">Device Characteristics</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><th>STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape (K234084)</th><th>STERRAD® SEALSURE® Chemical Indicator Tape (K111519)</th></tr>
<tr><td>Indications for Use</td><td>STERRAD™ SEALSURE™ Chemical Indicator Tape is a process indicator (ISO 11140-1:2014 [Type 1]) intended for use by health care providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD™ Sterilization Systems:<ul><li>STERRAD™ 100S</li><li>STERRAD NX™<ul><li>STANDARD AND ADVANCED Cycles with and without ALLClear™ Technology</li></ul></li><li>STERRAD™ 100NX<ul><li>STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology</li><li>ULTRA GI™ Cycle with Integrated ALLClear™ Technology</li></ul></li></ul>The color of the STERRAD SEALSURE Chemical Indicator Tape changes from red to gold (or lighter) indicated by comparator bar when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads.</td><td>STERRAD® SEALSURE® Chemical Indicator Tape (PN 14202) is a process indicator (ISO 11140-1:2005) intended for use by healthcare providers to secure non-woven sterilization packs and wraps to be sterilized in the STERRAD® Sterilization Systems.<table><tr><th>MODEL</th><th>CYCLE</th></tr><tr><td>STERRAD® 100S</td><td>Standard</td></tr><tr><td>STERRAD® 50</td><td>Standard</td></tr><tr><td>STERRAD® 200</td><td>Standard</td></tr><tr><td rowspan="2">STERRAD® NX</td><td>Standard</td></tr><tr><td>Advanced</td></tr><tr><td rowspan="4">STERRAD® 100NX</td><td>Standard</td></tr><tr><td>Flex</td></tr><tr><td>Express</td></tr><tr><td>DUO</td></tr></table>The color of the STERRAD® SEALSURE® Chemical Indicator Tape changes from red to gold (or lighter) when exposed to hydrogen peroxide and is intended to differentiate between processed and unprocessed loads.</td></tr>
<tr><td>Precaution</td><td>None</td><td>This product contains dry natural rubber.</td></tr>
<tr><td>Type of Chemical Indicator</td><td>Through-put process indicator</td><td>Same</td></tr>
</table>

| Device Characteristics | Subject Device | Predicate Device |
|---|---|---|
| | **STERRAD™ SEALSURE™ Chemical Indicator (CI) Tape (K234084)** | **STERRAD® SEALSURE® Chemical Indicator Tape (K111519)** |
| **Chemical Reaction** | Oxidation-reduction reaction specifically designed to react in the presence of hydrogen peroxide. The reaction is not reversible. | Same |
| **Packaging** | Six individually wrapped rolls per shipper box. | Same |
| **Design** | STERRAD System logo / CI square changes from red to gold (or lighter) upon exposure to the sterilant, hydrogen peroxide. | Same |
| **Distinct Color Change** | Red (pre-processed) to gold or lighter (post-processed) | Same |
| **Single Use Device** | Yes | Same |

**Summary of Non-Clinical Testing**

| Performance Testing | Description | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| **Chemical Indicator Functionality** | This study verified the Chemical Indicator functionality after processing in the ULTRA GI Cycle. | The Chemical Indicator will not change color when not exposed to the cycle parameter indication.<br>The Chemical Indicator will change color when exposed to cycle parameter indication. | Pass |
| **Residual Biocompatibility** | This study demonstrated the biocompatibility of the Chemical Indicator post processing in the ULTRA GI Cycle. | The residual hydrogen peroxide level shall be below the LOQ and exhibit mild toxicity or lower. | Pass |
| **End Point /Post Processing Color Stability** | This study demonstrated that the Chemical Indicator perform to the Type 1 | The chemical indicator shall perform to the Type 1 requirements of ISO 11140-1:2014. | Pass |

| | | | |
|---|---|---|---|
| | requirements of ISO 11140-1:2014. | | |
| **Tape Adhesion Strength** | This study verifies the adhesive strength after processing in the ULTRA GI Cycle. | The peel strength (adhesion-strength) must meet the acceptance criteria. | Pass |

**Summary**

The subject device, STERRAD SEALSURE Chemical Indicator (CI) Tape (14202NL), and its predicate utilize the same technology and verification/validation methods to achieve the intended use. The performance testing results indicate that including the ULTRA GI Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject device to be as safe and effective as the predicate.

**Conclusion**

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the existing legally marketed predicate device, K111519.

**510(k) Summary for K234084**
**Advanced Sterilization Products, Inc.**
**STERRAD VELOCITY™ Biological Indicator (BI) and STERRAD VELOCITY™ Reader**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

**General Information**

Submitter Name: Advanced Sterilization Products, Inc.

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Brandon Roberts
Senior Regulatory Affairs Specialist
Phone: (323) 590-4214
Email: brandon.roberts@asp.com

Date Prepared: July 2, 2024

**Device Name**

Proprietary Name: STERRAD VELOCITY™ Biological Indicator (BI) (43210) (60 count), STERRAD VELOCITY™ Biological Indicator (BI) (43210-30) (30 count) and STERRAD VELOCITY™ Reader (43220)

Common Name: Biological Indicator

Classification Name: Indicator, Biological Sterilization Process

Device Class: Class II

Product Code: FRC

CFR Section: 21 CFR 880.2800

**Predicate Device**

STERRAD VELOCITY® Biological Indicator/Process Challenge Device (BI/PCD) and STERRAD VELOCITY® Reader cleared under 510(k) K192025 on January 23, 2020.

**Device Description**

The STERRAD VELOCITY Biological Indicator (BI) is a self-contained biological indicator, used in conjunction with the STERRAD VELOCITY Reader, that is intended for frequent monitoring and/or periodic testing in STERRAD Sterilization Systems.

**Intended Use/Indications For Use**

The STERRAD VELOCITY™ Biological Indicator (BI)/Process Challenge Device (PCD), in conjunction with the STERRAD VELOCITY™ Reader, is intended to be used as a standard method for frequent monitoring and/or periodic testing of the following STERRAD™ Systems:

- STERRAD™ 100NX Sterilization System
  - STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology
  - ULTRA GI™ Cycle with Integrated ALLClear Technology (for frequent monitoring only).
- STERRAD NX™ Sterilization System
  - (STANDARD AND ADVANCED Cycles) with and without ALLClear™ Technology
- STERRAD™ 100S Sterilization System

**Comparison of Technological Characteristics**

| Device Characteristics | Subject Device<br>**STERRAD VELOCITY™ BI and STERRAD VELOCITY™ Reader (K234084)** | Predicate Device<br>**STERRAD VELOCITY™ BI/PCD and Reader (K192025)** |
|---|---|---|
| **Intended Use** | Monitoring of hydrogen peroxide gas plasma sterilization processes. | Same |
| **Indications for Use** | The STERRAD VELOCITY™ Biological Indicator (BI)/Process Challenge Device (PCD), in conjunction with the STERRAD VELOCITY™ Reader, is intended to be used as a standard method for frequent monitoring and/or periodic testing of the following STERRAD™ Systems:<br>• STERRAD™ 100NX Sterilization System<br>  ○ STANDARD, FLEX, EXPRESS, and DUO Cycles with and without ALLClear™ Technology<br>  ○ ULTRA GI™ Cycle with Integrated ALLClear Technology (for | STERRAD VELOCITY® Biological Indicator/Process Challenge Device, in conjunction with the STERRAD VELOCITY Reader, is intended to be used as a standard method for frequent monitoring and periodic testing of the following STERRAD Sterilization Systems:<br>• STERRAD® I00NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear® Technology<br>• STERRAD NX® (STANDARD and ADVANCED Cycles) with and without ALLClear® Technology<br>• STERRAD 100S |

| Device Characteristics | Subject Device<br>STERRAD VELOCITY™ BI and STERRAD VELOCITY™ Reader (K234084) | Predicate Device<br>STERRAD VELOCITY™ BI/PCD and Reader (K192025) |
|---|---|---|
| | frequent monitoring only).<br>• STERRAD NX™ Sterilization System<br>  ○ (STANDARD AND ADVANCED Cycles) with and without ALLClear™ Technology<br>• STERRAD™ 100S Sterilization System | |
| **Organism (Spore, Species, Strain)** | *Geobacillus stearothermophilus* ATCC 7953 | Same |
| **Viable Spore Population** | ≥ $1x10^6$ CFU/BI | Same |
| **Carrier Material** | Glass Fiber | Same |
| **Device Design** | Self-contained biological indicator. | Same |
| **Resistance Characteristics** | • Tested at 5 mg/L hydrogen peroxide: D-value $_{5mg/L}$: ≥ 1 second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1.<br>• Equal to or greater than the most difficult item routinely processed (biological model). | Same |
| **Rapid Readout Technology** | The α-glucosidase enzyme system is generated naturally during the growth of *Geobacillus stearothermophilus*. The α-glucosidase enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected in the reader. The fluorescence signal is used to determine a positive or negative result. | Same |
| **Incubation Temperature** | 57 +/- 2ºC | Same |
| **Incubation Time** | 15-minute fluorescence results read in STERRAD VELOCITY Reader and optional | Same |

| Device Characteristics | Subject Device | Predicate Device |
|---|---|---|
| | **STERRAD VELOCITY™ BI and STERRAD VELOCITY™ Reader (K234084)** | **STERRAD VELOCITY™ BI/PCD and Reader (K192025)** |
| | visual pH color change results at 5 to 7 days. | |
| **Holding Time** | Within 2 hours after sterilization cycle | Same |
| **Carrier growth inhibition/media growth promotion** | No bacteriostatic effects that inhibit the growth of the indicator microorganism | Same |
| **Chemical Indicator** | Type 1 process indicator changes color from red/pink to yellow or yellow with some red/orange/brown dots to indicate exposure to hydrogen peroxide. | Same |
| **Method of Fluorescence Detection** | UV LED, optical filters, with sensing by photodiode | Same |
| **Indicator of Adequate Sterilization Cycle** | "Negative" displayed on LCD Display | Same |
| **Indicators of Possible Sterilization Cycle Failure** | "Positive" displayed on LCD Display, Audible Alarm | Same |
| **Incubation Wells** | 8 incubation/reader wells | Same |
| **Voltage Range** | 100-240 Volts AC (12 Volt DC conversion for internal circuitry) | Same |
| **Product Safety** | UL/IEC 61010-1 | Same |
| **EMC Compliance** | FCC Part 15, Subpart B, Class A | Same |

**Summary of Non-Clinical Testing -Device**

| Performance Testing | Description | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| **Biological Indicator Performance** | This study verified the use of the Biological Indicator for use in frequent monitoring of the ULTRA GI Cycle. | General trend of increasing number of sterile BIs (growth and fluorescence) with increasing hydrogen peroxide injection volume. All BIs negative for fluorescence and growth at full cycle. | Pass |

| | | | |
|---|---|---|---|
| **Verification of Growth Inhibition of the Biological Indicator** | The study demonstrated that there is no inhibition effect on the STERRAD VELOCITY BI carrier and primary packaging materials processed through the ULTRA GI Cycle. | All test samples (positive controls) show growth. All negative controls show no growth. | Pass |
| **Chemical Indicator Functionality of Biological Indicator** | This study verified the Chemical Indicator functionality after processing in the ULTRA GI Cycle. | Chemical Indicator will not change color when not exposed to the cycle parameter indication. Chemical Indicator will change color when exposed to cycle parameter indication. | Pass |
| **Fluorescence Performance of Biological Indicator** | This study verified the accuracy of the Fluorescence results compared to growth positive BIs. | BI fluorescence-positive for greater than 97.0% of all growth-positive BIs. | Pass |

**Summary**

The subject devices STERRAD VELOCITY™ Biological Indicator (BI) (43210) (60 count), STERRAD VELOCITY™ Biological Indicator (BI) (43210-30) (30 count) and STERRAD VELOCITY™ Reader (43220), as well as their predicate, utilize the same technology and verification/validation methods to achieve the intended use. The performance testing results indicate that including the ULTRA GI Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject devices to be as safe and effective as the predicate.

**Conclusion**

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the existing legally marketed predicate device, K192025.

**510(k) Summary for K234084**
**Advanced Sterilization Products, Inc.**
**ULTRA GI™ Process Challenge Device (PCD) Vial**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

**General Information**

Submitter Name: Advanced Sterilization Products, Inc.

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Date Prepared: July 2, 2024

**Device Name**

Proprietary Name: ULTRA GI™ Process Challenge Device (PCD) (43400) (30 count)

Common Name: Process Challenge Device

Classification Name: Indicator, Biological Sterilization Process

Device Class: Class II

Product Code: FRC

CFR Section: 21 CFR 880.2800

**Predicate Device**

STERRAD VELOCITY® Biological Indicator/Process Challenge Device and STERRAD VELOCITY® Reader cleared under 510(k) K192025 on January 23, 2020.

**Device Description**

The assembled ULTRA GI PCD is composed of a vial that encapsulates the STERRAD VELOCITY Biological Indicator (BI). The vial creates a stronger resistance to the ULTRA GI Cycle. At the end of the cycle, the BI is removed from the vial and used in conjunction with the STERRAD VELOCITY Reader (software version 1139260417 or newer) to verify the effectiveness of the cycle. The ULTRA GI PCD Vial is only used for the ULTRA GI Cycle in STERRAD 100NX Sterilizers.

**Intended Use/Indications For Use**

The ULTRA GI™ Process Challenge Device (PCD) Vial is used with the STERRAD VELOCITY™ Biological Indicator (BI) for periodic testing and frequent monitoring of the ULTRA GI™ Cycle in the STERRAD™ 100NX Sterilization System with ALLClear™ Technology.

**Comparison of Technological Characteristics**

| Device Characteristics | Subject Device | Predicate Device |
|---|---|---|
| | **ULTRA GI™ PROCESS CHALLENGE DEVICE (PCD) Vial (K234084)** | **STERRAD VELOCITY™ BI/PCD and Reader (K192025)** |
| **Intended Use** | Monitoring of hydrogen peroxide gas plasma sterilization processes when used in conjunction with the STERRAD VELOCITY BI. | Same |
| **Indications for Use** | The ULTRA GI™ Process Challenge Device (PCD) Vial is used with the STERRAD VELOCITY™ Biological Indicator (BI) for periodic testing and frequent monitoring of the ULTRA GI™ Cycle in the STERRAD™ 100NX Sterilization System with ALLClear™ Technology. | STERRAD VELOCITY® Biological Indicator/Process Challenge Device, in conjunction with the STERRAD VELOCITY Reader, is intended to be used as a standard method for frequent monitoring and periodic testing of the following STERRAD Sterilization Systems:<br>• STERRAD® I00NX (STANDARD, FLEX, EXPRESS, and DUO Cycles) with and without ALLClear® Technology<br>• STERRAD NX® (STANDARD and ADVANCED Cycles) with and without ALLClear® Technology<br>• STERRAD 100S |
| **Vial Material** | Polypropylene (vial)<br>Buna-N (O-rings in vial)<br>Polyester+acrylic adhesive (label) | N/A |
| **Device Design** | ULTRA GI™ Process Challenge Device (PCD) Vial encapsulates the STERRAD VELOCITY™ Biological Indicator (BI). | Self-contained biological indicator. |

| Device Characteristics | Subject Device | Predicate Device |
|---|---|---|
| | **ULTRA GI™ PROCESS CHALLENGE DEVICE (PCD) Vial (K234084)** | **STERRAD VELOCITY™ BI/PCD and Reader (K192025)** |
| **Resistance Characteristics** | • Tested at 5 mg/L hydrogen peroxide: D-value $_{5mg/L}$: ≥ 1 second, using two D-value methods (Survivor Curve and Fraction Negative) per ISO 11138-1.<br>• Equal to or greater than the most difficult item routinely processed (biological model). | Same |

**Summary of Non-Clinical Testing - Biological Indicator/Process Challenge Device**

| Performance Testing | Description | Acceptance Criteria | Pass/Fail |
|---|---|---|---|
| **Hydrogen Peroxide Dose-Response and Sterilization Verification** | This study verified the design of the ULTRA GI PCD fluorescence. The BI readout in conjunction with the PCD vial provides a greater resistance in comparison to the biological model to the sterilization process using the ULTRA GI Cycle. | The general trend is an increasing number of sterile BIs (growth and fluorescence) with increasing hydrogen peroxide injection volume. All BIs are negative for fluorescence and growth at full cycle. | Pass |
| **Performance Qualification** | This study verified the fluorescence read performance when used for period testing and frequent monitoring. | The STERRAD VELOCITY BI/PCD fluorescence readout is qualified for performance in frequent monitoring and periodic testing indication. | Pass |

**Summary**

The subject device, ULTRA GI Process Challenge Device (PCD) Vial (43400) (30 count), and its predicate utilize the same technology and verification/validation methods to achieve the intended use. The performance testing results indicate that including the ULTRA GI Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject devices to be as safe and effective as the predicate.

**Conclusion**

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the existing legally marketed predicate device, K192025.