



November 4, 2024

Comercializadora Brever  
Clarisbeth Flores Lara  
Regulatory Advisor and Project Manager  
Omega 102 Local  
Leon, Guanajuato  
Mexico

Re: K240438

Trade/Device Name: CDB Hospital ® Sterilization Wrap (70 gsm);  
CDB Hospital ® Sterilization Wrap (44 gsm)

Regulation Number: 21 CFR 880.6850

Regulation Name: Sterilization Wrap

Regulatory Class: Class II

Product Code: FRG

Dated: January 5, 2024

Received: February 14, 2024

Dear Clarisbeth Flores Lara:

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](mailto: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: 2024.11.04 17:24:33  
-05'00'

for: Christopher K. Dugard, M.S.  
Assistant Director  
DHT4C: 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

## Indications for Use

510(k) Number (if known)

K240438

Device Name

CDB Hospital® Sterilization Wrap (70 gsm);

CDB Hospital® Sterilization Wrap (44 gsm)

Indications for Use (Describe)

CDB Hospital® Sterilization Wraps intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

- Pre-vacuum Steam 270°F/132°C for 4 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S
- Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)
- STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

Pre-Vacuum Steam Sterilization:

- Validated for dry time of 30 minutes for 44gsm.
- Validated for dry time of 30 minutes for 70gsm.
- Validated maximum weight of 6 lbs for 44 gsm.
- Validated maximum weight of 15 lbs for 70 gsm.
- All models of CDB Hospital® Sterilization Wraps validated for pre-vacuum steam sterilization with stainless steel lumens of 3 mm diameter or larger and length 400 mm or shorter as part of the load.

Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization:

All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100S sterilization with stainless steel lumens as part of the load with a maximum weight of 10.7lbs.

Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization:

All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100NX sterilization cycles are detailed below:

### VALIDATED ADVANCED STERILIZATION PRODUCTS (ASP) STERRAD® 100NX CYCLES

Advanced Sterilization Products (ASP) STERRAD® System and Cycle

Intended Load for 100NX Standard Cycle:

Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:

- An inside diameter of 0.7mm or larger and a length of 200mm or shorter of single channel stainless steel lumens.

Intended Load for 100NX Flex Cycle:

One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain:

A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (a maximum of two flexible endoscopes, one per tray per sterilization cycle).

Intended Load for 100NX Express Cycle:

Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or

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sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.

STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems:

- All models of CDB Hospital® Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed below.
- CDB Hospital® Sterilization Wraps were validated to be effectively aerated during the preprogrammed STERIS Amsco V-PRO® Sterilization Cycles.

#### VALIDATED STERIS AMSCO® V-PRO CYCLES

##### STERIS Amsco® V-PRO Cycle

##### Intended Load for Lumen Cycle:

Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.

##### Intended Load for Non Lumen Cycle:

Non lumened reusable metal and non-metal medical devices.

##### Intended Load for Flexible Cycle:

Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration:

- 1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 3 mm or larger and a length of 450 mm or shorter.
- 2.) An additional tray containing non-lumened medical devices.

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

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**510(k) SUMMARY**  
**(as required by 21 CFR § 807.92)**  
**K240438**

- I. Submitter:** Comercializadora Brever  
Ms. Clarisbeth Flores Lara  
Omega 102 Local  
Leon, Guanajuato Mexico  
Phone: 477-331-1478  
c.flores@cdbhospital.com  
Date Prepared: 1 November 2024
- II. Device:**
- |                              |                                                                                           |
|------------------------------|-------------------------------------------------------------------------------------------|
| <b>Trade Name of Device:</b> | CDB Hospital ® Sterilization Wrap (70 gsm);<br>CDB Hospital ® Sterilization Wrap (44 gsm) |
| <b>Common or Usual Name:</b> | Sterilization Wrap                                                                        |
| <b>Classification Name:</b>  | Sterilization Wrap                                                                        |
| <b>Regulation Number:</b>    | 21 CFR 880.6850                                                                           |
| <b>Device Class:</b>         | Class II                                                                                  |
| <b>Regulation Name:</b>      | Sterilization Wrap                                                                        |
| <b>Product Code:</b>         | FRG                                                                                       |
- III. Predicate Device:**
- **K171533** – Ahlstrom Nonwovens LLC Reliance® Tandem and Reliance® Solo

**IV. Device Description:**

The CDB Hospital ® Sterilization Wraps are square or rectangular nonwoven sheets produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The CDB Hospital ® Sterilization Wraps' SMS fabric is made of 100% polypropylene, blue color, and are separated into two distinct product offerings:

**CDB Hospital® Sterilization Wraps, 44gsm:** Consist of two sheets of SMS wrap (light blue and dark blue), ultrasonically bonded together along two edges for convenient simultaneous wrapping of one or a collection of medical devices that will be sterilized following standard health care practices.

**CDB Hospital® Sterilization Wraps, 70gsm:** Consist of two sheets of SMS wrap (light blue and dark blue), ultrasonically bonded together along two edges for convenient simultaneous wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices.

CDB Hospital® Sterilization Wraps are composed of polypropylene with the addition of light blue and dark blue pigment and an antistatic treatment. The CDB Hospital ® Sterilization Wraps allow a sterilized package of medical devices to be opened aseptically. This product is over-the-counter use.

## **V. Indications for Use:**

CDB Hospital® Sterilization Wraps intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

- Pre-vacuum Steam 270°F/132°C for 4 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S
- Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)
- STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

### **Pre-Vacuum Steam Sterilization:**

- Validated for dry time of 30 minutes for 44gsm.
- Validated for dry time of 30 minutes for 70gsm.
- Validated maximum weight of 6 lbs for 44 gsm.
- Validated maximum weight of 15 lbs for 70 gsm.
- All models of CDB Hospital® Sterilization Wraps validated for pre-vacuum steam sterilization with stainless steel lumens of 3 mm diameter or larger and length 400 mm or shorter as part of the load.

### **Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization:**

All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100S sterilization with stainless steel lumens as part of the load with a maximum weight of 10.7lbs.

### **Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization:**

All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100NX sterilization cycles are detailed below:

#### **VALIDATED ADVANCED STERILIZATION PRODUCTS (ASP) STERRAD® 100NX CYCLES**

Advanced Sterilization Products (ASP) STERRAD® System and Cycle

##### **Intended Load for 100NX Standard Cycle:**

Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:

- An inside diameter of 0.7mm or larger and a length of 200mm or shorter of single channel stainless steel lumens.

##### **Intended Load for 100NX Flex Cycle:**

One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain:

A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (a maximum of two flexible endoscopes, one per tray per sterilization cycle).

**Intended Load for 100NX Express Cycle:**

Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.

**STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems:**

- All models of CDB Hospital® Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed below.
- CDB Hospital® Sterilization Wraps were validated to be effectively aerated during the preprogrammed STERIS Amsco V-PRO® Sterilization Cycles.

**VALIDATED STERIS AMSCO® V-PRO CYCLES****STERIS Amsco® V-PRO Cycle****Intended Load for Lumen Cycle:**

Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.

**Intended Load for Non Lumen Cycle:**

Non lumened reusable metal and non-metal medical devices.

**Intended Load for Flexible Cycle:**

Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration:

- 1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 3 mm or larger and a length of 450 mm or shorter.
- 2.) An additional tray containing non-lumened medical devices.

**VI. Comparison of Technological Characteristics with the Predicate Device:**

| Element of Comparison      | Predicate Device – K171533<br>RELIANCE® Tandem and Solo Sterilization Wrap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Subject Device – K240438<br>CDB Hospital ® Sterilization Wrap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Comparison |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>Indications for Use</b> | <p>Ahlstrom Reliance® Tandem and Solo Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:</p> <ul style="list-style-type: none"> <li>• Pre-vacuum Steam 270°F/132°C for 4 minutes</li> <li>• Gravity Steam 250°F/121°C for 30 minutes</li> <li>• 100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes</li> <li>• Advanced Sterilization Products (ASP) STERRAD® 100S</li> <li>• Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)</li> <li>• STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)</li> </ul> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.</p> <p><b>Pre-Vacuum Steam Sterilization:</b></p> <ul style="list-style-type: none"> <li>• Validated for dry time of 20 minutes for Models T100/S100, T200/S200, T300/S300.</li> <li>• Validated for dry time of 30 minutes for Models T400/S400, T500/S500, T600/S600.</li> <li>• All models of Reliance® Tandem and Solo validated for pre-vacuum steam sterilization with stainless steel lumens as part of the load with a maximum weight of 25lbs dependent on the model.</li> </ul> | <p>CDB Hospital ® Sterilization Wraps intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:</p> <ul style="list-style-type: none"> <li>• Pre-vacuum Steam 270°F/132°C for 4 minutes</li> <li>• Advanced Sterilization Products (ASP) STERRAD® 100S</li> <li>• Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)</li> <li>• STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)</li> </ul> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.</p> <p><b>Pre-Vacuum Steam Sterilization:</b></p> <ul style="list-style-type: none"> <li>• Validated for dry time of 30 minutes for 44gsm.</li> <li>• Validated for dry time of 30 minutes for 70gsm.</li> <li>• Validated maximum weight of 6 lbs for 44 gsm.</li> <li>• Validated maximum weight of 15 lbs for 70 gsm.</li> </ul> <p>All models of CDB Hospital ® Sterilization Wraps validated for pre-vacuum steam sterilization with stainless steel lumens of 3 mm diameter or larger and length 400 mm or shorter as part of the load.</p> | Similar    |

| <p><b>Gravity Steam Sterilization:</b></p> <ul style="list-style-type: none"><li>Validated for dry times of 20 minutes for Models T100/S100, T200/S200, T300/S300.</li><li>Validated for dry times of 30 minutes for Models T400/S400.</li><li>Models T100/S100, T200/S200, T300/S300, T400/S400 of Reliance® Tandem and Solo validated for gravity steam sterilization with stainless steel lumens as part of the load with a maximum weight of 25lbs dependent on the model.</li><li>Models T500/S500 and T600/S600 are not validated for use for gravity steam sterilization.</li></ul> <p><b>Ethylene Oxide Sterilization:</b></p> <ul style="list-style-type: none"><li>Validated for aeration time of 8 hours at 55oC</li><li>All models of Reliance® Tandem and Solo validated for ethylene oxide sterilization with stainless steel lumens as part of the load with a maximum weight of 25lbs dependent on the model.</li></ul> <p><b>Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization</b></p> <ul style="list-style-type: none"><li>All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100S sterilization with stainless steel lumens as part of the load with a maximum weight of 10.7lbs dependent on the model.</li></ul> <p><b>Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization</b></p> <ul style="list-style-type: none"><li>All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100NX sterilization cycles detailed in Table 1.</li></ul> <p><b>Table 1: Validated Advanced Sterilization Products (ASP) STERRAD® 100NX Cycles</b></p> <table><tr><th>Advanced Sterilization Products (ASP) STERRAD® System and Cycle</th><th>Intended Load</th></tr><tr><td>100NX Standard Cycle</td><td>Reusable metal and non-metal medical devices, including up to 10 lumens of the following</td></tr></table> | Advanced Sterilization Products (ASP) STERRAD® System and Cycle                          | Intended Load | 100NX Standard Cycle | Reusable metal and non-metal medical devices, including up to 10 lumens of the following | <p><b>Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization:</b></p> <p>All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100S sterilization with stainless steel lumens as part of the load with a maximum weight of 10.7lbs.</p> <p><b>Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization:</b></p> <p>All models of CDB Hospital® Sterilization Wraps validated with ASP STERRAD® 100NX sterilization cycles are detailed below:</p> <p><b>VALIDATED ADVANCED STERILIZATION PRODUCTS (ASP) STERRAD® 100NX CYCLES</b></p> <p><b>Advanced Sterilization Products (ASP) STERRAD® System and Cycle</b></p> <p><b>Intended Load for 100NX Standard Cycle:</b></p> <p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"><li>An inside diameter of 0.7mm or larger and a length of 200mm or shorter of single channel stainless steel lumens.</li></ul> <p><b>Intended Load for 100NX Flex Cycle:</b></p> <p>One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain: A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (a maximum of two flexible endoscopes, one per tray per sterilization cycle).</p> <p><b>Intended Load for 100NX Express Cycle:</b></p> <p>Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.</p> <p><b>STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO max</b></p> |
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| Advanced Sterilization Products (ASP) STERRAD® System and Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Intended Load                                                                            |               |                      |                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 100NX Standard Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Reusable metal and non-metal medical devices, including up to 10 lumens of the following |               |                      |                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                | dimensions per chamber load: <ul style="list-style-type: none"><li>• An inside diameter of 0.7mm or larger and a length of 500mm or shorter of single-channel stainless steel lumens.</li></ul> | <p><b>Low Temperature Sterilization Systems:</b></p> <ul style="list-style-type: none"><li>• All models of CDB Hospital® Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed below.</li><li>• CDB Hospital® Sterilization Wraps were validated to be effectively aerated during the preprogrammed STERIS Amsco V-PRO® Sterilization Cycles.</li></ul> <p><b>VALIDATED STERIS AMSCO® V-PRO CYCLES</b></p> <p>STERIS Amsco® V-PRO Cycle</p> <p><b>Intended Load for Lumen Cycle:</b><br/>Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.</p> <p><b>Intended Load for Non Lumen Cycle:</b><br/>Non lumened reusable metal and non-metal medical devices.</p> <p><b>Intended Load for Flexible Cycle:</b><br/>Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration:</p> <ol style="list-style-type: none"><li>1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 3 mm or larger and a length of 450 mm or shorter.</li><li>2.) An additional tray containing non-lumened medical devices.</li></ol> |                           |               |             |
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| 100NX Flex Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain: <ul style="list-style-type: none"><li>• A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle)</li></ul> |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                           |               |             |
| 100NX Express Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.                                                                                                                                                  |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                           |               |             |
| <p><b>STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO max Low Temperature Sterilization Systems</b></p> <ul style="list-style-type: none"><li>• All models of Reliance® Tandem and Solo Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed in Table 2.</li><li>• Reliance® Tandem and Solo Sterilization Wraps were validated to be effectively aerated during the pre-programmed STERIS Amsco V-PRO® Sterilization Cycles.</li></ul> |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                           |               |             |
| <p><b>Table 2: Validated STERIS Amsco® V-PRO Cycles</b></p> <table><tr><th>STERIS Amsco® V-PRO Cycle</th><th>Intended Load</th></tr><tr><td>Lumen Cycle</td><td>Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger</td></tr></table>                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | STERIS Amsco® V-PRO Cycle | Intended Load | Lumen Cycle |
| STERIS Amsco® V-PRO Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Intended Load                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                           |               |             |
| Lumen Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger                                                                                                                                                                                                                            |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                           |               |             |

|                                                 |                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                  |         |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                 |                                                                                                                                                                                                                                                                                                                                   | and a length of 400mm or shorter.                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                  |         |
|                                                 | Non Lumen Cycle                                                                                                                                                                                                                                                                                                                   | Non lumened reusable metal and non-metal medical devices.                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                  |         |
|                                                 | Flexible Cycle                                                                                                                                                                                                                                                                                                                    | Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration:<br>1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 1 mm or larger and a length of 850 mm or shorter.<br>2.) An additional tray containing non-lumened medical devices. |                                                                                                                                                                                                                                                                                  |         |
| <b>Regulation, Classification, Product Code</b> | <i>Regulation Number:</i> 21 CFR 880.6850<br><i>Classification Name:</i> Sterilization Wrap<br><i>Regulatory Class:</i> II<br><i>Product Code:</i> FRG                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                    | <i>Regulation Number:</i> 21 CFR 880.6850<br><i>Classification Name:</i> Sterilization Wrap<br><i>Regulatory Class:</i> II<br><i>Product Code:</i> FRG                                                                                                                           | Same    |
| <b>Device Design</b>                            | Nonwoven sheets produced using a three-layer SMS (spunbond-meltblown-spunbond) process.<br><br>Reliance® Tandem: One sheet of SMS wrap<br><br>Reliance® Solo: Consists of two sheets of SMS wrap                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                    | Two nonwoven sheets of wrap (light blue and dark blue). Each sheet is produced using a three-layer spunbond-meltblown-spunbond (SMS) process.                                                                                                                                    | Similar |
| <b>Method for bonding SMS layers</b>            | Reliance® Solo: Consists of two sheets of SMS wrap, ultrasonically bonded together along two edges                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                    | two sheets of SMS wrap (light blue and dark blue) are ultrasonically bonded together along two edges.                                                                                                                                                                            | Similar |
| <b>Materials</b>                                | Polypropylene spunbond-meltblown-spunbond (SMS) fabric                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                    | Spunbond-meltblown-spunbond (SMS) nonwoven polypropylene material                                                                                                                                                                                                                | Similar |
| <b>Models</b>                                   | Reliance® Tandem and Solo Models: T100/S100, T200/S200, T300/S300 T400/S400, T500/S500, T600/S600                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                    | 44 gsm<br>70 gsm                                                                                                                                                                                                                                                                 | Similar |
| <b>Product Color and Dimensions</b>             | Blue, Green<br><br>9 x 9 in                      9 x 9 in<br>12 x 12 in                    12 x 12 in<br>15 x 15 in                    15 x 15 in<br>18 x 18 in                    18 x 18 in<br>20 x 20 in                    20 x 20 in<br>24 x 24 in                    24 x 24 in<br>30 x 30 in                    30 x 30 in |                                                                                                                                                                                                                                                                                                                                                                                    | Blue<br><br>12 x 12 in                    36 x 36 in<br>15 x 15 in                    40 x 40 in<br>18 x 18 in                    45 x 45 in<br>20 x 20 in                    48 x 48 in<br>24 x 24 in                    54 x 54 in<br>30 x 30 in                    54 x 72 in | Similar |
| <b>Prescription vs OTC</b>                      | OTC                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                    | OTC                                                                                                                                                                                                                                                                              | Same    |

|                                 |                 |                                                                          |      |
|---------------------------------|-----------------|--------------------------------------------------------------------------|------|
| <b>Single Use vs. Reusable</b>  | Single use only | Single use only                                                          | Same |
| <b>Biocompatibility</b>         | Pass            | Applicable parts of ISO 10993 - Biological evaluation of medical devices | Same |
| <b>Maintenance of Sterility</b> | 180 days        | 180 days                                                                 | Same |

## VII. Summary of Non-Clinical Testing:

Performance data for the CDB Hospital Sterilization Wrap included a series of nonclinical tests, each associated with specific unique codes. These tests were conducted to demonstrate continued conformance with the microbial barrier properties. The CDB Hospital Sterilization Wraps underwent a comprehensive range of tests including Low Temperature Efficacy, Steam Efficacy, Shelf Life, Aerosol Challenge, and Biocompatibility / Cytotoxicity. The testing was conducted to validate the wraps' ability to maintain sterility of pack contents after sterilization, assessing different sterilization methods and shelf life durations up to 180 days under standard conditions. All results met the defined acceptance criteria.

Also, please note that all testing refers to the same product(s) that are manufactured by Comercializadora Brever, S.A. de C.V.

| <b>Test Item</b>                             | <b>Test Standard Methods</b> | <b>Remark</b>     |
|----------------------------------------------|------------------------------|-------------------|
| <b>Basis Weight</b>                          | ASTM D3776/D3776M-20         | Meets requirement |
| <b>Tearing Strength</b>                      | ASTM D5587- 15(2019)         | Meets requirement |
| <b>Lint Generation</b>                       | ISO 9073-10:2003             | Meets requirement |
| <b>Bacterial Filtration Efficiency (BFE)</b> | ASTM F2101- 23               | Meets requirement |
| <b>Hydrostatic Pressure</b>                  | AATCC Test Method 127-2018   | Meets requirement |

|                                                                      |                                        |                   |
|----------------------------------------------------------------------|----------------------------------------|-------------------|
| <b>Air Permeability</b>                                              | ASTM D737- 18                          | Meets requirement |
| <b>Sterilant penetration- BI incubation</b>                          | ANSI/AAMI/ISO 11138-7                  | Meets requirement |
| <b>Maintenance of Package Sterility- Sterility Test</b>              | USP-NF 2022<br><71>                    | Meets requirement |
| <b>Maintenance of Package Sterility- Microbial Aerosol Challenge</b> | ASTM F1608- 21                         | Meets requirement |
| <b>Biocompatibility- Cytotoxicity and Irritation</b>                 | ISO 10993-5:2009,<br>ISO 10993-23:2021 | Meets requirement |

**VIII. Summary for Clinical Testing:**

Not Applicable

**IX. Conclusions:**

The conclusion drawn from the 510(k) from the nonclinical tests shall demonstrate that the subject devices included in the 510(k) submission, CDB Hospital® Sterilization Wrap, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K171533 (RELIANCE® Tandem and Solo Sterilization Wrap).