December 11, 2018

Cardinal Health 200 LLC
Jillian Connery
Manager Regulatory Affairs
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K181174
Trade/Device Name: Cardinal Health Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: October 30, 2018
Received: November 01, 2018

Dear Jillian Connery:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181174

Device Name
Cardinal Health™ Sterilization Wrap

Indications for Use *(Describe)*
The Cardinal Health™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:
• Gravity steam at 250°F/121°C for 30 minutes.
• Pre-vacuum steam at 270°F/132°C for 4 minutes.
• 100% ethylene oxide (EO) with a concentration of 725-735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.
• Advanced Sterilization Products (ASP) STERRAD® 100S system.
• Advanced Sterilization Products (ASP) STERRAD® NX system, Standard and Advanced Cycles.
• Advanced Sterilization Products (ASP) STERRAD® 100NX System, Standard, Flex, Express and Duo Cycles.
• Advanced Sterilization Products (ASP) STERRAD® 200 System.
• Lumen, Non Lumen, and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus, STERIS V-PRO® maX and STERIS V-PRO® 60 Low Temperature Sterilization Systems.
• TSO3 STERIZONE® VP4 System Cycle 1 (Refer to Table 5 for load)
The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.
For gravity steam sterilization and pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600. Models CH400, CH500 and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.
For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55°C. Models CH400, CH500 and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less.
All models of the Cardinal Health™ Sterilization Wrap have been validated for Advanced Sterilization Products (ASP) STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.
All models of the Cardinal Health™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX cycles in Table 1. All models of the Cardinal Health™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® 200 in Table 1.
All models of the Cardinal Health™ Sterilization Wrap have been validated for use with the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 cycles in Tables 2 and 3. The Cardinal Health™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 sterilization cycles.
All models of Cardinal Health™ Sterilization Wrap have been validated for use with the TSO3 STERIZONE® VP4 system with the intended loads as described in Table 4.

Table 1- Dimensions, types and models

Dimensional Specifications	Cardinal Health™ Sterilization Wrap Models					
	CH100	CH200	CH300	CH400	CH500	CH600
12 in. x 12 in. (30 cm. x 30 cm.)	1* 2 3	1 2 3				
15 in. x 15 in. (38 cm. x 38 cm.)	1 2 3					
18 in. x 18 in. (45 cm. x 45 cm.)	1 2 3	1 2 3		1	1 2 3	
20 in. x 20 in. (50 cm. x 50 cm.)	1 2 3					
24 in. x 24 in. (60 cm. x 60 cm.)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	
30 in. x 30 in. (76 cm. x 76 cm.)	1 2 3	1 2 3	1 2 3	1	1 2 3	
36 in. x 36 in. (91 cm. x 91 cm.)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
40 in. x 40 in. (101 cm. x 101 cm.)	1 2 3	1 2 3	1 2 3	1 2 3		1 2 3
45 in. x 45 in. (114 cm. x 114 cm.)	1 2 3		1 2 3	1 2 3	1 2 3	1 2 3
48 in. x 48 in. (121 cm. x 121 cm.)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
54 in. x 54 in. (137 cm. x 137 cm.)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
60 in. x 60 in. (152 cm. x 152 cm.)					1 2 3	
54 in. x 72 in. (137 cm. x 182 cm.)	1	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
54 in. x 90 in. (137 cm. x 228 cm.)					1 2 3	

*Product configurations:

1. Single Layer Sterilization Wrap 2. Dual Layer Sterilization Wrap 3. Two Color Sterilization Wrap - Double-layer wrap

Table 2 – Validated Advanced Sterilization Products STERRAD® NX, STERRAD® 100NX and STERRAD® 200 Sterilization Cycles and Intended Loads

Advanced Sterilization Products (ASP) STERRAD® System	Maximum Recommended Chamber Load	Intended Load
ASP STERRAD® NX Standard Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens
ASP STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter
ASP STERRAD® 100NX Standard Cycle	21.4 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens (A maximum of five lumens per tray per sterilization cycle)
ASP STERRAD® 100NX Flex Cycle	12.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene 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)
ASP STERRAD® 100NX Express Cycle	10.7 lbs	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
ASP STERRAD® 100NX Duo Cycle	13.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter
ASP STERRAD® 200	36.48 lbs	Reusable metal and non-metal medical devices, including up to 12 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens • an inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens • an inside diameter of 6 mm or larger and a length of 310 mm or shorter of a single-channel Teflon®/Polyethylene lumen

Table 3: Validated STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX Cycles and Intended Loads

STERIS V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Table 4: Validated STERIS V-PRO® 60 Cycles and Intended Loads

STERIS V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	11 lbs	Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: • Single channel of an inside diameter of 0.77 mm or larger with a length of 410 mm or shorter • Dual channel of an inside diameter of 0.77 mm or larger with a length of 410 mm or shorter • Triple channel of an inside diameter of 1.2 mm or larger with a length of 275 mm or shorter and 1.8 mm or larger with a length of 310 mm or shorter and 2.8 mm or larger with a length of 317 mm or shorter
Non-Lumen Cycle	12 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	No additional load other than intended tray contents	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two configurations: 1. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and silicone mat: • The flexible endoscope(s) may contain either a single channel or dual channel with an inside diameter of 1 mm or larger and a length of 990 mm or shorter

Table 5: Validated TSO3 STERIZONE® VP4 Cycle 1 Loads

Validation load #	Load Description	Load weight[1] [1]Excluding the 25 lb loading rack
1	Validation load #1 consisted of general medical instruments, representing the following geometries: • Clamp • Serrated surface • Box-lock • Handle • Button • Pivot hinge • Stopcock Type of packaging used: wrapped plastic tray, including silicone mats and brackets, Pouch General medical instruments were spread out over three trays, six pouches and one wrapped instrument.	11 lb
2	Validation load #2 consisted of general medical instruments, representing the following geometries: • Gliding mechanism • Hinges and screws • Serrated surface • Luer-lock • Spring • Rigid non-lumen scopes Type of packaging used: wrapped aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch General medical instruments were spread out over one container, three trays, and six pouches.	20 lb
3	Validation load #3 consisted of **three** single channel flexible endoscopes (Ureteroscope) with inside diameter of 1.0 mm and length of 850 mm, packaged individually in wrapped trays or containers, including appropriate silicone brackets or mats. Eight general medical instruments, each packaged in a pouch, were added.	23 lb
4	Validation load #4 consisted of up to **15** rigid or semi-rigid channeled instruments in the presence of other packaged medical devices. Three double channel semi-rigid endoscopes (ureterscope – 0.7 mm x 500 mm and 1.1 mm x 500 mm) were packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. Additional rigid channel instruments or stainless steel rigid lumens were added to each package. Two additional general medical instruments, each packaged in a pouch, were added.	19 lb
5	Validation load #5 consisted in **two** single channel flexible endoscopes; one Ureteroscope with inside diameter of 1.0 mm and length of 850 mm and Bronchoscope with inside diameter of 1.8 mm and length of 830 mm, and **one** double channel semi-rigid endoscope (ureterscope – 0.7 mm x 500 mm and 1.1 mm x 500 mm) packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. No additional items were added.	21 lb
6	Validation load #6 consisted of general medical instruments, representing the following geometries: • Distal end (swivel parts) • Hinge with screw • Cannula General medical instruments packaged in one aluminum sterilizer container.	9 lb
7	Validation load #7 consisted of general medical instruments, representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments, spread out over three aluminum sterilization containers, each weighing 25 lb.	75 lb

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Cardinal Health™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 3651 Birchwood Waukegan, IL 60085
Regulatory Affairs Contact:	Jillian Connery
Telephone Number:	(614) 757-4045
Fax Number:	(847) 887-2461
Date summary Prepared:	December 10, 2018
Trade Name:	Cardinal Health™ Sterilization Wrap
Classification:	Class II per 21 CFR § 880.6850
Classification Name:	Sterilization Wrap
Common Name:	Sterilization Wrap
Product Code:	FRG
510(k) number:	K181174
Predicate Device:	K151445, K151788, K161910 – Cardinal Health™ Sterilization Wrap for use with Pre-Vacuum Steam (4 min/270°F), Gravity Steam (30 min/250°F), 100% Ethylene Oxide (EO), Advanced Sterilization Products (ASP) STERRAD® 100S, STERRAD® 200, STERRAD® NX, STERRAD® 100NX Systems, and STERIS V-PRO® 1, V-PRO® 1 Plus, and V-PRO® maX Low Temperature Sterilization Systems

Description:

Cardinal Health™ Sterilization Wraps are made from 100% polypropylene spunbond-meltblown-spunbond (SMS) nonwoven fabric. The sterilization wrap is provided in six different material basis weights (models) of four product offerings in various dimensions. Cardinal Health™ Sterilization Wrap, Single Layer is comprised of a single sheet or one layer of SMS fabric. Cardinal Health™ Sterilization Wrap, Dual Layer and Cardinal Health™ Sterilization Wrap, TwoColor are comprised of two single layer sheets of SMS fabric ultrasonically bonded along two opposing sides. The wrap design allows for use of the sequential or simultaneous double-wrapping technique per recommendations from ANSI/AAMI ST79:2017 and allows for a sterilized pack to be opened aseptically. All models utilize the same material technology. These products are a single-use device and for over-the-counter use only.

They are intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- Gravity steam at 250°F/121°C for 30 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S System
- Advanced Sterilization Products (ASP) STERRAD® 200 System
- Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles
- Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus, STERIS V-PRO® maX and STERIS V-PRO® 60 Low Temperature Sterilization Systems
- TSO3 STERIZONE® VP4 System Cycle 1(Refer to Table 5 for Load)

Materials and Mode of Operation:

Principle mode of operation: Cardinal Health™ Sterilization Wraps have sufficient breathability to allow sterilization of the enclosed medical device and have sufficient barrier to maintain sterility of the enclosed devices, demonstrated for 365 days. Per AAMI ST79, two layers of sterilization wrap are required for use either non-sequentially using double layer sterilization wrap or sequentially / simultaneously using single layer sterilization wrap. The closure of the sterile barrier system is achieved through the resulting tortuous path from wrapping.

The Cardinal Health™ Sterilization Wraps are available in the models and dimensions below. The mode of operation, material dimensions, types and models are the same for both the predicate device and the subject device.

Table 1- Dimensions, types and models

EN – Dimensional Specifications FR – Spécifications des dimensions ES – Especificaciones dimensionales	Cardinal Health™ EN – Wrap Models		ES – Modelos de envolturas		FR – Modèles d'emballage	
	CH100	CH200	CH300	CH400	CH500	CH600
12 in. x 12 in. (30 cm x 30 cm)	1 2 3	1 2 3				
15 in. x 15 in. (38 cm x 38 cm)	1 2 3					
18 in. x 18 in. (45 cm x 45 cm)	1 2 3	1 2 3		1	1 2 3	
20 in. x 20 in. (50 cm x 50 cm)	1 2 3					
24 in. x 24 in. (60 cm x 60 cm)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	
30 in. x 30 in. (76 cm x 76 cm)	1 2 3	1 2 3	1 2 3	1	1 2 3	
36 in. x 36 in. (91 cm x 91 cm)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
40 in. x 40 in. (101 cm x 101 cm)	1 2 3	1 2 3	1 2 3	1 2 3		1 2 3
45 in. x 45 in. (114 cm x 114 cm)	1 2 3		1 2 3	1 2 3	1 2 3	1 2 3
48 in. x 48 in. (121 cm x 121 cm)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
54 in. x 54 in. (137 cm x 137 cm)	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
60 in. x 60 in. (152 cm x 152 cm)					1 2 3	
54 in. x 72 in. (137 cm x 182 cm)	1	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3
54 in. x 90 in. (137 cm x 228 cm)					1 2 3	

EN - 1. Single Layer Sterilization Wrap 2. Dual Layer Sterilization Wrap 3. Two Color Sterilization Wrap

Product Description

The Cardinal Health™ Sterilization Wrap is made from 100% polypropylene spunbond-meltblown-spunbond (SMS) trilaminate nonwoven fabric. Cardinal Health™ Sterilization Wrap, Single Layer is comprised of a single sheet or one layer of SMS fabric. Cardinal Health™ Sterilization Wrap, Dual Layer and Cardinal Health™ Sterilization Wrap, Two Color are comprised of two single layer sheets of SMS fabric ultrasonically bonded along two opposing sides.

In accordance with standard hospital practices, two sheets are used to wrap a medical device or a collection of medical devices for sterilization. When wrapping with the Cardinal Health™ Sterilization Wrap, Single Layer model, two sheets are required. Cardinal Health™ Sterilization Wrap, Dual Layer or Cardinal Health™ Sterilization Wrap, Two Color models allow for

wrapping with two sheets simultaneously. Cardinal Health™ Sterilization Wrap allows for the use of the sequential or simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

Indications for Use

Cardinal Health™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- Gravity steam at 250°F/121°C for 30 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S System
- Advanced Sterilization Products (ASP) STERRAD® 200 System
- Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles
- Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus, STERIS V-PRO® maX and STERIS V-PRO® 60 Low Temperature Sterilization Systems
- TSO3 STERIZONE® VP4 System Cycle 1 (Refer to Table 5 for Load)

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

For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600. Models CH400, CH500 and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.

For gravity steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600.

For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55 °C. Models CH400, CH500 and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less.

All models of Cardinal Health™ Sterilization Wrap have been validated for Advanced Sterilization Products (ASP) STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.

All models of Cardinal Health™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® 200, STERRAD® NX and STERRAD® 100NX cycles with the intended loads as described in Table 2.

All models of Cardinal Health™ Sterilization Wrap have been validated for use with the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 cycles with the intended loads as described in Tables 3 and 4. Cardinal Health™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 sterilization cycles.

All models of Cardinal Health™ Sterilization Wrap have been validated for use with the TSO3 STERIZONE® VP4 system with the intended loads as described in Table 5.

Table 2 – Validated Advanced Sterilization Products STERRAD® NX, STERRAD® 100NX and STERRAD® 200 Sterilization Cycles and Intended Loads

Advanced Sterilization Products (ASP) STERRAD® System	Maximum Recommended Chamber Load	Intended Load
ASP STERRAD® NX Standard Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens
ASP STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter
ASP STERRAD® 100NX Standard Cycle	21.4 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens (A maximum of five lumens per tray per sterilization cycle)
ASP STERRAD® 100NX Flex Cycle	12.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene 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)
ASP STERRAD® 100NX Express Cycle	10.7 lbs	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
ASP STERRAD® 100NX Duo Cycle	13.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

ASP STERRAD® 200	36.48 lbs	Reusable metal and non-metal medical devices, including up to 12 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens • an inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens • an inside diameter of 6 mm or larger and a length of 310 mm or shorter of a single-channel Teflon®/Polyethylene lumen

Table 3: Validated STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX Cycles and Intended Loads

STERIS V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Table 4: Validated STERIS V-PRO® 60 Cycles and Intended Loads

STERIS V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	11 lbs	Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: • Single channel of an inside diameter of 0.77 mm or larger with a length of 410 mm or shorter • Dual channel of an inside diameter of 0.77 mm or larger with a length of 410 mm or shorter • Triple channel of an inside diameter of 1.2 mm or larger with a length of 275 mm or shorter and 1.8 mm or larger with a length of 310 mm or shorter and 2.8 mm or larger with a length of 317 mm or shorter
Non-Lumen Cycle	12 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	No additional load other than intended tray contents	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two configurations: 1. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and silicone mat: • The flexible endoscope(s) may contain either a single channel or dual channel with an inside diameter of 1 mm or larger and a length of 990 mm or shorter

Table 5: Validated TSO3 STERIZONE® VP4 Cycle 1 Loads

Validation load #	Load Description	Load weight[1] [1]Excluding the 25 lb loading rack
1	Validation load #1 consisted of general medical instruments, representing the following geometries: • Clamp • Serrated surface • Box-lock • Handle • Button • Pivot hinge • Stopcock Type of packaging used: wrapped plastic tray, including silicone mats and brackets, Pouch General medical instruments were spread out over three trays, six pouches and one wrapped instrument.	11 lb
2	Validation load #2 consisted of general medical instruments, representing the following geometries: • Gliding mechanism • Hinges and screws • Serrated surface • Luer-lock • Spring • Rigid non-lumen scopes Type of packaging used: wrapped aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch General medical instruments were spread out over one container, three trays, and six pouches.	20 lb
3	Validation load #3 consisted of **three** single channel flexible endoscopes (Ureteroscope) with inside diameter of 1.0 mm and length of 850 mm, packaged individually in wrapped trays or containers, including appropriate silicone brackets or mats. Eight general medical instruments, each packaged in a pouch, were added.	23 lb
4	Validation load #4 consisted of up to **15** rigid or semi-rigid channeled instruments in the presence of other packaged medical devices. Three double channel semi-rigid endoscopes (ureterscope – 0.7 mm x 500 mm and 1.1 mm x 500 mm) were packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. Additional rigid channel instruments or stainless steel rigid lumens were added to each package. Two additional general medical instruments, each packaged in a pouch, were added.	19 lb
5	Validation load #5 consisted in **two** single channel flexible endoscopes; one Ureteroscope with inside diameter of 1.0 mm and length of 850 mm and Bronchoscope with inside diameter of 1.8 mm and length of 830 mm, and **one** double channel semi-rigid endoscope (ureterscope – 0.7 mm x 500 mm and 1.1 mm x 500 mm) packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. No additional items were added.	21 lb
6	Validation load #6 consisted of general medical instruments, representing the following geometries: • Distal end (swivel parts) • Hinge with screw • Cannula General medical instruments packaged in one aluminum sterilizer container.	9 lb
7	Validation load #7 consisted of general medical instruments, representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments, spread out over three aluminum sterilization containers, each weighing 25 lb.	75 lb

Table 6: Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]					
		Pre-Vacuum & Gravity Steam, EO and STERIZONE® VP4	Advanced Sterilization Products (ASP) STERRAD® 100S	Advanced Sterilization Products (ASP) STERRAD® NX and 100NX	Advanced Sterilization Products (ASP) STERRAD® 200	STERIS V-PRO® 1, 1Plus, maX	STERIS V-PRO® 60
CH100	Very light weight package (for example: towel packs or batteries).	3 lbs	3 lbs	10.7 lbs	9.12 lbs	3 lbs	3 lbs
CH200	Light weight package (for example: telescope with light cord).	6 lbs	6 lbs	10.7 lbs	9.12 lbs	6.5 lbs	6 lbs
CH300	Light to moderate weight package (for example: general use medical instruments).	9 lbs	9.7 lbs	10.7 lbs	9.12 lbs	9 lbs	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments).	13 lbs	9.7 lbs	10.7 lbs	9.12 lbs	9.1 lbs	12 lbs
CH500	Heavy weight package (for example: general use medical instruments).	17 lbs	9.7 lbs	10.7 lbs	9.12 lbs	9.1 lbs	12 lbs
CH600	Very heavy weight package (for example: general use medical instruments).	25 lbs	9.7 lbs	10.7 lbs	9.12 lbs	9.1 lbs	12 lbs

The following loads were used in the pre-vacuum steam Sterility Validation Studies:
• **CH100:** 16 huck towels (17 in. x 29 in.).
• **CH200:** 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.).
• **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
• **CH400:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 8 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH500:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the gravity steam Sterility Validation Studies:
• **CH100**: 1 tray liner (23 in. x 19.5 in.), 1 lb of metal mass in a 13 in. x 9.2 in. x 3.2 in. tray.
• **CH200**: 1 tray liner (23 in. x 19.5 in.), 3 lbs of metal mass in a 13 in. x 9.2 in. x 3.2 in. tray.

• **CH300**: 1 tray liner (23 in. x 19.5 in.), 6 lbs of metal mass in a 22 in. x 10.6 in. x 2.4 in. tray.
• **CH400**: 1 tray liner (23 in. x 19.5 in.), 10 lbs of metal mass in a 22 in. x 10.6 in. x 2.4 in. tray.
• **CH500**: 1 tray liner (23 in. x 19.5 in.), 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH600**: 1 tray liner (23 in. x 19.5 in.), 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the EO Sterility Validation Studies:
• **CH100:** 16 huck towels (17 in. x 29 in.).
• **CH200:** 2 huck towels (17 in. x 29 in.), 2 fluid-resistant drapes (108 in. x 88 in.), 2.5 lbs of metal mass.
• **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
• **CH400:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 7.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH500:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 11.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 100S Sterility Validation Studies:
• **CH100:** Metal instruments.
• **CH200 - CH600:** 15 in. x 10 in. x 1.2 in. tray containing metal instruments.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 200 Sterility Validation Studies:
• **CH100 - CH600:** 23 in. x 11 in. x 4 in. tray containing metal instruments.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX Sterility Validation Studies:
• **CH100 - CH600:** 23 in. x 11 in. x 4 in. tray containing metal instruments.

The following loads were used in the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX Sterility Validation Studies:
• **CH100:** Metal instruments.
• **CH200 - CH600:** 17 in. x 10 in. x 3.5 in. tray containing metal instruments.

The following loads were used in the STERIS V-PRO® 60 Sterility Validation Studies:
• **CH100 - CH600:** 21 in. x 10 in. x 3.5 in. tray containing metal instruments.

The following loads were used in the STERIZONE® VP4 Sterility Validation Studies:
• **CH100:** 10 in. x 6 in. x 1.5 in. plastic tray containing metal instruments.

• **CH200:** 15 in. x 10 in. x 1.5 in. plastic tray containing metal instruments.
• **CH300:** 20 in. x 9.2 in. x 2.8 in. plastic tray containing metal instruments.
• **CH400:** 20 in. x 9 in. x 4 in. metal tray containing metal instruments.
• **CH500:** 23 in. x 11 in. x 3.5 in. metal tray containing metal instruments.
• **CH600:** 21 in. x 10 in. x 5 in. metal tray containing metal instruments.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 6.

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the Cardinal Health™ Sterilization Wraps.

Table 7: Summary of the Technological Characteristics and Performance

Summary of the technological characteristics and the Performance of the device compared to the predicate device			
Element of comparison	**PREDICATE** **Cardinal Health™ Sterilization Wrap (K151445, K151788, K161910)**	**PROPOSED** **Cardinal Health™ Sterilization Wrap (K181174)**	**Comparison to predicate**
Manufacturer	Cardinal Health Inc.	Cardinal Health Inc.	Same
Regulation/ Product Code	Sterilization Wrap: 880.6850/ FRG	Sterilization Wrap: 880.6850/ FRG	Same
Trade Name	Cardinal Health™ Sterilization Wrap	Cardinal Health™ Sterilization Wrap	Same
Intended Use	Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using: • Pre-vacuum steam at 270°F/132°C for 4 minutes • Gravity steam at 250°F/121°C for 30 minutes • 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes • Advanced Sterilization Products (ASP) STERRAD® 100S System • Advanced Sterilization Products (ASP)	Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using: • Pre-vacuum steam at 270°F/132°C for 4 minutes • Gravity steam at 250°F/121°C for 30 minutes • 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes • Advanced Sterilization Products (ASP) STERRAD® 100S System • Advanced Sterilization Products (ASP)	Same. The new device has been additionally tested for use with STERIS V-PRO® 60 System and TSO3 STERIZONE® VP4 System Cycle 1.

	STERRAD® 200 System • Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles • Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles • Lumen, Non Lumen, and Flexible Cycles by the STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.	STERRAD® 200 System • Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles • Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles • Lumen, Non Lumen, and Flexible Cycles by the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 Low Temperature Sterilization Systems • TSO3 STERIZONE® VP4 System Cycle 1(Refer to Table 5 for Load) The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.	

Prescription vs. OTC	OTC	OTC	Same
Single Use Only vs. Reusable	Single use only	Single Use only	Same
Material Composition	Polypropylene fabric using SMS (spunbound-meltdown-spunbound) production process	Polypropylene fabric using SMS (spunbound-meltdown-spunbound) production process	Same
Chemical Properties	Polypropylene with blue pigment and antistatic treatment Polypropylene with green pigment and antistatic treatment	Polypropylene with blue pigment and antistatic treatment Polypropylene with green pigment and antistatic treatment	Same
Device Design	**Dual layer, fold-over:** Double layer wrap comprised of a single sheet of blue pigmented SMS fabric that has been folded over in half and ultrasonically sealed to itself on the three non-folded edges **Dual Layer:** Double-layer wrap comprised of two separate sheets of blue pigmented SMS fabric that have been ultrasonically sealed on two opposing edges **Single Layer:** Single-layer wrap comprised of a single sheet of blue pigmented SMS fabric	**Dual layer, fold-over:** Double layer wrap comprised of a single sheet of blue pigmented SMS fabric that has been folded over in half and ultrasonically sealed to itself on the three non-folded edges **Dual Layer:** Double-layer wrap comprised of two separate sheets of blue pigmented SMS fabric that have been ultrasonically sealed on two opposing edges **Single Layer:** Single-layer wrap comprised of a single sheet of blue pigmented SMS fabric	Same

	Two Color: Double-layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of green pigmented SMS fabric that have been ultrasonically sealed on two opposing edges	**Two Color:** Double-layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of green pigmented SMS fabric that have been ultrasonically sealed on two opposing edges	
Sterilization Parameters	Pre-vacuum steam at 270ºF/132ºC for 4 minutes Gravity steam at 250°F/121°C for 30 minutes 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131ºF/55ºCand 40%-80% relative humidity for 60 minutes Advanced Sterilization Products (ASP) STERRAD® 100S System Advanced Sterilization Products (ASP) STERRAD® 200 System Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles	Pre-vacuum steam at 270ºF/132ºC for 4 minutes Gravity steam at 250°F/121°C for 30 minutes 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131ºF/55ºCand 40%-80% relative humidity for 60 minutes Advanced Sterilization Products (ASP) STERRAD® 100S System Advanced Sterilization Products (ASP) STERRAD® 200 System Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles	Same. The new device has been additionally tested for use with STERIS V-PRO® 60 System and TSO3 STERIZONE® VP4 System Cycle 1.

	Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX Low Temperature Sterilization Systems	Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 Low Temperature Sterilization Systems TSO3 STERIZONE® VP4 System Cycle 1	
Models/ Dimensions	Six basis weights models Fourteen sizes (See Table 8 for dimensions)	Six basis weights models Fourteen sizes (See Table 8 for dimensions)	Same
Maximum Wrapped Package Content Weights (corresponding to minimum to maximum basis weights of wrap models)	Pre-vacuum Steam: 3 to 25 pounds Gravity Steam: 3 to 25 pounds EO: 3 to 25 pounds STERRAD® 100S: 3 to 9.7 pounds STERRAD® 200: 9.12 pounds STERRAD® NX: 10.7 pounds STERRAD® 100NX: 10.7 pounds STERIS V-PRO® 1, V-PRO® 1 Plus and V-	Pre-vacuum Steam: 3 to 25 pounds Gravity Steam: 3 to 25 pounds EO: 3 to 25 pounds STERRAD® 100S: 3 to 9.7 pounds STERRAD® 200: 9.12 pounds STERRAD® NX: 10.7 pounds STERRAD® 100NX: 10.7 pounds STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® maX: 3 to 9.1 pounds	Same

	PRO® maX: 3 to 9.1 pounds	STERIS V-PRO® 60: 3 to 12 pounds STERIZONE® VP4: 3 to 25 pounds	
Maintenance of Sterility	Prevac steam = 365 days Gravity steam = 365 days EO = 365 days Sterrad 100S = 365 days Sterrad 200 = 30 days Sterrad NX = 365 days Sterrad 100NX = 365 days VPRO 1 = 365 days VPRO 1 Plus = 365 days VPRO maX = 365 days	VPRO 60 = 365 days VP4 = 365 days	Same
Sterilant Penetration, ANSI/AAMI TIR 12, ANSI/ AAMI ST79/A4	Negative for growth	Negative for growth	Same
Maintenance of package sterility (Microbial Aerosol Challenge) ANSI/AAMI TIR 12, ANSI/ AAMI /A4	Negative for growth	Negative for growth	Same
Event related shelf life, ANSI/AAMI TIR 12, ANSI/ AAMI ST79/A4, Premarket Notification 510(k) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA	No growth	No growth	Same

Biocompatibility – Irritation, ISO 10993-10	Negligible irritant	Negligible irritant	Same
Leachability, ISO 6588-2	Non-Aged - Extract Appearance: Clear, free of color - pH: Comparable to negative control Aged 30 days - Extract Appearance: Clear, free of color - pH: Comparable to negative control	Non-Aged - Extract Appearance: Clear, free of color - pH: Comparable to negative control Aged 30 days - Extract Appearance: Clear, free of color - pH: Comparable to negative control	Same
Residuals, ISO 10993-7	None detected	None detected	Same
Sterilization Efficacy ANSI/AAMI TIR 12, ANSI/ AAMI ST79/A4	Negative for growth	Negative for growth	Same
Material Compatibility, Premarket Notification 510(k) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA, - - Basis weight, ASTM D3776/D3776M-09 - Air permeability, ASTM D737-04	Compatible	Compatible	Same

- Material burst strength, ASTM D3786 - Grab Tensile strength, ASTM D5034-09 - Trapezoidal Tear strength, ASTM D5587-15 - Hydrostatic Pressure, AATC127-2014			

Cardinal Health™ Sterilization Wrap is manufactured according to the Device Description in Table 8 below:

Table 8 – Device Description

Wrap Dimensions	Side A	Side B	Tolerance
12”x12”	12”	12”	±0.5”
15”x15”	15”	15”	±0.5”
18”x18”	18”	18”	±0.5”
20”x20”	20”	20”	±0.5”
24”x24”	24”	24”	±0.5”
30”x30”	30”	30”	±0.5”
36”x36”	36”	36”	±0.5”
40”x40”	40”	40”	±1”
45”x45”	45”	45”	±1”
48”x48”	48”	48”	±1”
54”x54”	54”	54”	±1”
60”x60”	60”	60”	±1”
54”x72”	54”	72”	±1”
54”x90”	54”	90”	±1”

Summary of Non-Clinical Testing

Performance testing included sterilization efficacy, event related maintenance of package sterility, physical properties, and biocompatibility in compliance with the methods of ISO 10993.
Extensive performance testing has been completed on Cardinal Health™ Sterilization Wrap in this submission of the new indications for use with STERIS V-PRO® 60 and TSO3 STERIZONE® VP4. Data from testing demonstrates that the Cardinal Health™ Sterilization Wrap allows for sterilization of the enclosed contents and also maintains sterility of the enclosed devices after sterilization with the STERIS V-PRO® 60 and TSO3 STERIZONE® VP4 systems.
Physical properties testing (Basis weight, Air permeability, Grab tensile strength, Trapezoidal tear strength, Bursting strength and Hydrostatic pressure) included in this submission also supports the fact that the integrity of the wrap properties is not compromised after sterilization by the indicated sterilization processes and storage because the polypropylene material is inert and very stable. These material compatibility results also demonstrate that the device meets the requirements of ISO 11607.
The proposed device (Cardinal Health™ Sterilization Wrap) has been evaluated for biocompatibility according to ISO 10993 test methods and is considered toxicologically acceptable for its intended use. All materials used in the Cardinal Health™ Sterilization Wrap have been evaluated through irritation, leachability and residuals testing after sterilization by STERIS V-PRO® 60 and TSO3 STERIZONE® VP4 sterilization systems.
The data shows that the biocompatibility of the Cardinal Health™ Sterilization Wrap following sterilization by STERIS V-PRO® 60 and TSO3 STERIZONE® VP4 sterilization systems is substantially equivalent to the biocompatibility of the predicate.
Performance testing demonstrates that both devices:

- Have the same intended use
- Have the same material composition
- Have the same physical and chemical properties
- Have the same dimensions
- Demonstrate maintenance of package sterility
- The physical properties of all wrap models have been characterized both before and after exposure to sterilization by STERIS V-PRO® 60 and TSO3 STERIZONE® VP4. The data demonstrates that the Cardinal Health™ Sterilization Wrap is compatible with the STERIS V-PRO® 60 and TSO3 STERIZONE® VP4 sterilization systems.

Table 9: Summary of Non-Clinical Testing

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence		
Non-Clinical Test	**Standard**	**Results Summary**
Microbial Barrier Properties		
Maintenance of Package Sterility (Microbial Aerosol Challenge)	ANSI/AAMI TIR12, ANSI/AAMI ST79 A1&A2	Negative for growth
Event Related Shelf Life Test – 365 days	ANSI/AAMI TIR12, ANSI/AAMI ST79 A1&A2	No growth
Material Compatibility with Indicated Sterilization Method - Basis weight, - Air permeability - Material burst strength - Grab Tensile strength - Trapezoidal Tear strength - Hydrostatic Pressure	- ASTM D3776/D3776M-09 (2013) - ASTM D737-04 (2012) - ASTM D3786 - ASTM D5034-09 (2013) - ASTM D5587-15 - AATC127-2014 -	Compatible
Post-Sterilization Biocompatibility Testing		
Residuals	ISO 10993-7	None detected
Leachability	ISO 6588-2	Non-Aged - Extract Appearance: Clear, free of color - pH: Comparable to negative control Aged 30 days - Extract Appearance: Clear, free of color - pH: Comparable to negative control
Irritation	ISO 10993, 10:2010	Negligible irritant

Summary of Clinical Testing:
Not applicable

Conclusions Drawn from Non-Clinical Data:
Based on the conclusions drawn from the intended use, technological characteristics, and non-clinical tests conducted, results demonstrate that the subject device is as safe, as effective and performs at least as well as the legally marketed device Cardinal Health™ Sterilization Wrap.