



Food and Drug Administration
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October 30, 2015

Cardinal Health 200, LLC
Ms. Megan Middaugh
Regulatory Affairs Manager
1500 Waukegan Road
Waukegan, IL 60085

Re: K151788

Trade/Device Name: Cardinal Health™ Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: October 8, 2015
Received: October 9, 2015

Dear Ms. Middaugh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151788

Device Name

Cardinal Health™ Sterilization Wrap

Indications for Use (Describe)

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:

- 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, Standard, Flex, Express, and DUO cycles
- Lumen, Non Lumen, and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus and STERIS 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 devices until it is used.

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 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 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® NX and STERRAD® 100NX cycles in Table 1.

All models of Cardinal Health™ Sterilization Wrap have been validated for use with the STERIS V-PRO® cycles in Table 2. Cardinal Health™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS V-PRO® sterilization cycles.

Table 1 – Validated Advanced Sterilization Products STERRAD® NX® and STERRAD® 100NX® 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

Table 2: Validated STERIS V-PRO® 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: <ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> • 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 3: Wrap Model Recommendations¹

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

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 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 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® 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® Sterility Validation Studies:

- CH100: Metal instruments.
- CH200 - CH600: 17 in. x 10 in. x 3.5 in. tray containing metal instruments.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 3.

¹Individual 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.

²It 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.

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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Waukegan, IL 60085
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterilization Wrap

Manufacturer: Cardinal Health 200, LLC
1500 Waukegan Road
Waukegan, IL 60085

Regulatory Affairs Contact: Megan Middaugh
1500 Waukegan Road
Waukegan, IL 60085

Telephone Number: (847) 887-6812

Fax Number: (847) 887-2461

Date summary Prepared: October 26, 2015

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

Predicate Device: K132060 - DuraBlue™ Sterilization Wrap for use with Pre-Vacuum Steam (4 min/270°F) & 100% Ethylene Oxide (EO), Advanced Sterilization Products (ASP) STERRAD® 100S, STERRAD® 100NX, and STERRAD® NX Systems, and STERIS Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus, and Amsco® V-PRO® maX Low Temperature Sterilization Systems

Description:

Cardinal Health™ Sterilization Wraps are made from 100% polypropylene spunbond-meltblown-spunbond (SMS) trilaminate nonwoven fabric. The sterilization wrap is provided in six different material basis weights (models) of four product offerings in various dimensions. The wrap design allows for use of the sequential or simultaneous double-wrapping technique per recommendations from ANSI/AAMI ST79:2010 and also allows for a sterilized pack to be opened aseptically. All models utilize the same material technology. This product is 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:

- 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, Standard, Flex, Express, and DUO cycles
- Lumen, Non Lumen, and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus and STERIS V-PRO® maX Low Temperature Sterilization Systems

Extensive performance testing has been completed on Cardinal Health™ Sterilization Wrap in this submission of the new indication for use with gravity steam sterilization. Successful completion of the sterilization performance tests demonstrated that the wrap allows for sterilization of the enclosed contents and also maintains sterility of the enclosed devices. Physical properties testing 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.

The trade name of Cardinal Health DuraBlue™ Sterilization Wrap has been changed to Cardinal Health™ Sterilization Wrap. This name change has no impact on the safety and efficacy of the product.

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:

- 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, Standard, Flex, Express, and DUO cycles
- Lumen, Non Lumen, and Flexible Cycles in the STERISV-PRO® 1, STERIS V-PRO® 1 Plus and STERIS 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 devices until used.

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 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 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® NX and STERRAD® 100NX cycles with the intended loads as described in Table 1.

All models of Cardinal Health™ Sterilization Wrap have been validated for use with the STERIS V-PRO® cycles with the intended loads as described in Table 2. Cardinal Health™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS V-PRO® sterilization cycles.

Table 1 – Validated Advanced Sterilization Products STERRAD® NX® and STERRAD® 100NX® 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

Table 2: Validated STERIS Amsco® V-PRO® 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: <ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> • 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 3: Wrap Model Recommendations¹

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

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 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 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® 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® Sterility Validation Studies:

- **CH100:** Metal instruments.
- **CH200 - CH600:** 17 in. x 10 in. x 3.5 in. tray containing metal instruments.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 3.

¹Individual 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.

²It 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.

Substantial Equivalence

The proposed Cardinal Health™ Sterilization Wrap is substantially equivalent to the predicate devices. 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
- Performance and safety attributes are substantially equivalent to the predicate. The physical properties of all wrap models have been characterized both before and after exposure to gravity steam sterilization. The resulting data supports the conclusion that Cardinal Health™ Sterilization Wrap sterilized with gravity steam is substantially equivalent to Cardinal Health DuraBlue™ Sterilization Wrap sterilized with the pre-vacuum steam. The data demonstrates that the Cardinal Health™ Sterilization Wrap is compatible with the gravity steam sterilization.

Table 4: Overall Comparison to Predicate Device

Element of Comparison	<u>PREDICATE</u> Cardinal Health DuraBlue™ Sterilization Wrap (K132060)	<u>PROPOSED</u> Cardinal Health™ Sterilization Wrap	Comparison to Predicate
Manufacturer	Cardinal Health Inc.	Same	Substantially Equivalent
Regulation/ Product Code	Sterilization Wrap: 880.6850 / FRG	Same	Substantially Equivalent
Trade Name	Cardinal Health DuraBlue™ Sterilization Wrap	Cardinal Health™ Sterilization Wrap	Substantially Equivalent
Intended Use	<p>DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using:</p> <ul style="list-style-type: none"> • 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®, 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 <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.</p>	<p>Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using:</p> <ul style="list-style-type: none"> • 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®, 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 <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.</p>	Substantially Equivalent

Element of Comparison	<u>PREDICATE</u> Cardinal Health DuraBlue™ Sterilization Wrap (K132060)	<u>PROPOSED</u> Cardinal Health™ Sterilization Wrap	Comparison to Predicate
Material Composition	Polypropylene fabric using SMS (spunbond-meltblown-spunbond) production process	Same	Substantially Equivalent
Physical Properties	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	<p>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</p> <p>Dual Layer: Double-layer wrap comprised of two separate sheets of blue pigmented SMS fabric that have been ultrasonically sealed on two opposing edges</p> <p>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 ()</p> <p>Single Layer: Single-layer wrap comprised of a single sheet of blue pigmented SMS fabric</p>	Substantially Equivalent
Chemical Properties	Polypropylene with blue pigment and antistatic treatment	<p>Polypropylene with blue pigment and antistatic treatment</p> <p>Polypropylene with green pigment and antistatic treatment</p>	Substantially Equivalent

Element of Comparison	<u>PREDICATE</u> Cardinal Health DuraBlue™ Sterilization Wrap (K132060)	<u>PROPOSED</u> Cardinal Health™ Sterilization Wrap	Comparison to Predicate
Sterilization Parameters	<p>Pre-vacuum steam at 270°F/132°C for 4 minutes</p> <p>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</p> <p>Advanced Sterilization Products (ASP) STERRAD® 100S System</p> <p>Advanced Sterilization Products (ASP) STERRAD® NX® System, Standard and Advanced Cycles</p> <p>Advanced Sterilization Products (ASP) STERRAD® 100NX®, Standard, Flex, Express, and DUO cycles</p> <p>Lumen, Non Lumen, and Flexible Cycles in the STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® MAX Low Temperature Sterilization Systems</p>	<p>Gravity steam at 250°F/121°C for 30 minutes</p> <p>Pre-vacuum steam at 270°F/132°C for 4 minutes</p> <p>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</p> <p>Advanced Sterilization Products (ASP) STERRAD® 100S System</p> <p>Advanced Sterilization Products (ASP) STERRAD® NX® System, Standard and Advanced Cycles</p> <p>Advanced Sterilization Products (ASP) STERRAD® 100NX®, Standard, Flex, Express, and DUO cycles</p> <p>Lumen, Non Lumen, and Flexible Cycles in the STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® MAX Low Temperature Sterilization Systems</p>	Substantially Equivalent
Models/ Dimensions	<p>Six basis weights models</p> <p>Fourteen sizes (See Table 4 for dimensions)</p>	Same	
Maximum Wrapped Package Content Weights	<p>Pre-vacuum Steam: 3 to 25 pounds</p> <p>EO: 3 to 25 pounds</p> <p>STERRAD® 100S: 3 to 9.7 pounds</p> <p>STERRAD® NX®: 10.7 pounds</p> <p>STERRAD® 100NX®: 10.7 pounds</p> <p>STERIS V-PRO®: 3 to 9.1 pounds</p>	<p>Gravity Steam: 3 to 25 pounds</p> <p>Pre-vacuum Steam: 3 to 25 pounds</p> <p>EO: 3 to 25 pounds</p> <p>STERRAD® 100S: 3 to 9.7 pounds</p> <p>STERRAD® NX®: 10.7 pounds</p> <p>STERRAD® 100NX®: 10.7 pounds</p> <p>STERIS V-PRO®: 3 to 9.1 pounds</p>	

Element of Comparison	<u>PREDICATE</u> Cardinal Health DuraBlue™ Sterilization Wrap (K132060)	<u>PROPOSED</u> Cardinal Health™ Sterilization Wrap	Comparison to Predicate
Sterilization Efficacy	Pass	Pass	Substantially Equivalent
Microbial Barrier Properties	Pass	Pass	Substantially Equivalent
Maintenance of Sterility	PASS – 365 days for Pre-vacuum Steam, Ethylene Oxide, STERRAD® 100S, STERRAD® NX, STERRAD® 100NX, STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® MAX Low	PASS- 30 days for Gravity Steam PASS – 365 days for Pre-vacuum Steam, Ethylene Oxide, STERRAD® 100S, STERRAD® NX, STERRAD® 100NX, STERIS V-PRO® 1, V- PRO® 1 Plus and V- PRO® MAX Low	Substantially Equivalent
Material Compatibility	Compatible	Compatible	Substantially Equivalent
Biocompatibility (Cytotoxicity ISO 10993-5: 2009; Sensitization, ISO 10993-10: 2010; Irritation, ISO 10993-10:2010)	Non-cytotoxic Non-sensitizing Non-irritating	Non-cytotoxic Non-sensitizing Non-irritating	Substantially Equivalent

Summary of Testing

Cardinal Health™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA’s Guidance Document Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002) in this submission and the predicate Premarket Notifications.

Testing included sterilization efficacy, event related maintenance of package sterility, physical properties, and biocompatibility in compliance with the methods of ISO 10993. Data from testing demonstrates that the performance of the Cardinal Health™ Sterilization Wrap intended for use with the additional indication of gravity steam sterilization is substantially equivalent to the predicate device.

Table 5: Performance Testing of Proposed Cardinal Health™ Sterilization Wrap

Performance Properties		Results
Sterilization Efficacy		PASS
Microbial Barrier Properties	Aerosol Challenge	PASS
	Maintenance of Sterility	PASS- 30 days for Gravity Steam PASS – 365 days for Pre-vacuum Steam, Ethylene Oxide, STERRAD® 100S, STERRAD® NX, STERRAD® 100NX, STERIS V-PRO® 1, V-PRO® 1 Plus and V-PRO® MAX Low
Material Compatibility with Indicated Sterilization Method		Compatible
Biocompatibility	Cytotoxicity, ISO 10993-5: 2009	Non-cytotoxic
	Irritation, ISO 10993-10:2010	Non- irritating
	Sensitization, ISO 10993-10: 2010	Non-sensitizing

Conclusions:

Based on the results of the biocompatibility, sterilization, and physical performance testing, Cardinal Health™ Sterilization Wrap is safe for its intended use. The Cardinal Health™ Sterilization Wrap is substantially equivalent to the predicate device, in terms of general intended use, physical performance testing, material composition, sterilization process and compatibility, and configurations/dimensions.