DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2017

Cardinal Health 200, LLC
Tatyana Bogdan
Director, Regulatory Affairs
1500 Waukegan Road
Waukegan, Illinois 60085

Re: K161910
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: March 10, 2017
Received: March 17, 2017

Dear Tatyana Bogdan:

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,

Michael J. Ryan -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161910

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 by using:

• Advanced Sterilization Products (ASP) STERRAD® 200 System

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.

All models of the Cardinal Health™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® 200 in Table 1.

Table 1 – Validated Advanced Sterilization Products STERRAD® 200 Sterilization Cycle and Intended Load

Advanced Sterilization Products (ASP) STERRAD® System	Maximum Recommended Chamber Load	Intended Load
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 2: Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]
		Advanced Sterilization Products (ASP) STERRAD® 200
CH100	Very light weight package (for example: towel packs or batteries).	9.12 lbs
CH200	Light weight package (for example: telescope with light cord).	9.12 lbs
CH300	Light to moderate weight package (for example: general use medical instruments).	9.12 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments).	9.12 lbs
CH500	Heavy weight package (for example: general use medical instruments).	9.12 lbs
CH600	Very heavy weight package (for example: general use medical instruments).	9.12 lbs

[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.

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.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 2.

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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Cardinal Health
1500 Waukegan Road
Waukegan, IL 60085
cardinalhealth.com

510(k) SUMMARY

Cardinal Health™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 1500 Waukegan Road Waukegan, IL 60085
Regulatory Affairs Contact:	Tatyana Bogdan 1500 Waukegan Road Waukegan, IL 60085
Telephone Number:	(847) 887-6812
Fax Number:	(847) 887-2461
Date summary Prepared:	April 20, 2017
Product 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:	K151445 - Cardinal Health™ Sterilization Wrap
Reason for 510(k) Submission:	Additional product offering of a legally marketed device

Device Description:

The Cardinal Health™ Sterilization Wraps are made from 100% polypropylene spunbond-meltblown-spunbond (SMS) trilaminate nonwoven fabric. The sterilization wraps are 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, Two Color 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 ST79:2010 and also 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 the Advanced Sterilization Products (ASP) STERRAD® 200 System.

The Cardinal Health™ Sterilization Wraps are available in the models and dimensions below.

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**	

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

Indications for Use

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 by using:

- Advanced Sterilization Products (ASP) STERRAD® 200 System

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

All models of the Cardinal Health™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® 200 in Table 1.

Table 1 – Validated Advanced Sterilization Products STERRAD® 200 Cycle and Intended Load

Advanced Sterilization Products (ASP) STERRAD® System	Maximum Recommended Chamber Load	Intended Load
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 2: Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]
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CH500	Heavy weight package (for example: general use medical instruments).	9.12 lbs
CH600	Very heavy weight package (for example: general use medical instruments).	9.12 lbs

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.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 2.

[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 3: Summary of the Technological Characteristics and Performance

Summary of the technological characteristics and Performance of the device compared to the predicate device		
Element of Comparison	**PREDICATE** **Cardinal Health™ Sterilization Wrap (K151445)**	**PROPOSED** **Cardinal Health™ Sterilization Wrap (K161910)**
Manufacturer	Cardinal Health Inc.	Cardinal Health Inc.
Regulation/ Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG
Trade Name	Cardinal Health™ Sterilization Wrap	Cardinal Health™ Sterilization Wrap
Intended Use	Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using: • Advanced Sterilization Products (ASP) STERRAD® 200 System The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.	Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using: • Advanced Sterilization Products (ASP) STERRAD® 200 System 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
Single Use Only vs. Reusable	Single Use Only	Single Use Only
Material Composition	Polypropylene fabric using SMS (spunbond-meltblown-spunbond) production process	Polypropylene fabric using SMS (spunbond-meltblown-spunbond) production process
Chemical Properties	Polypropylene with blue pigment and antistatic treatment	Polypropylene with blue pigment and antistatic treatment Polypropylene with green pigment and antistatic treatment

Element of Comparison	PREDICATE Cardinal Health™ Sterilization Wrap (K151445)	PROPOSED Cardinal Health™ Sterilization Wrap (K161910)
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 **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	Advanced Sterilization Products (ASP) STERRAD® 200 System	Advanced Sterilization Products (ASP) STERRAD® 200 System
Models/ Dimensions	Six basis weights models Fourteen sizes	Six basis weights models Fourteen sizes
Maximum Wrapped Package Content Weights	STERRAD® 200: 9.12 pounds	STERRAD® 200: 9.12 pounds
Maintenance of Sterility	STERRAD® 200: 365 days	STERRAD® 200: 365 days
Sterilant Penetration	Passed	Passed
Biocompatibility – Cytotoxicity, ISO 10993-5: 2009	Non-cytotoxic , under the conditions of the test	Non-cytotoxic , under the conditions of the test
Biocompatibility - Sensitization, ISO 10993-10: 2010	Non-sensitizing, under the conditions of the test	Non-sensitizing, under the conditions of the test
Biocompatibility - Irritation, ISO 10993-10:2010	Non-irritating, under the conditions of the test	Non-irritating, under the conditions of the test

Discussion of Similarities and Differences:

The proposed Cardinal Health™ Sterilization Wrap is substantially equivalent in intended use, indication for use, materials, characteristics, dimensions and product features to the predicate device Cardinal Health™ Sterilization Wrap (K151445). Both devices have identical manufacturing processes.

The difference between the proposed and the predicate device is an additional product offering, Two Color, Dual-layer wrap to the previously cleared and currently marketed Single Color Dual-layer sterilization wrap. The additional product offering is the same design as the Single Color, Dual Layer offering with one exception; there is one sheet of green pigmented SMS fabric and one sheet of blue SMS that has been ultrasonically sealed on two opposing edges. This change was made to address customer preferences for end user identification of instrument trays for aesthetic purposes only.

This pigment difference does not impact safety or efficacy of the product. The Two Color Sterilization Wrap offering is of the same design, technology, base raw material, and has the same intended use, with the only difference being the addition of a green pigment. There has been no change to the performance from one color to two color. Non-clinical data as seen in Table 4 demonstrates that the additional product offering is substantially equivalent to predicate device.

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. 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 Advanced Sterilization Products (ASP) STERRAD® 200 System.

Table 4: Summary of Non-Clinical Testing

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence		
Study		**Results Summary**
Microbial Barrier Properties	Maintenance of Package Integrity Test (Microbial Aerosol Challenge)	PASSED
	Event Related Shelf Life Test – 365 days	PASSED
Sterrad® 200 Sterilant Penetration		PASSED
Material Compatibility with Indicated Sterilization Method Basis weight, ASTM D3776-09 Air permeability, ASTM D737-04 (2012) Material burst strength, ASTM D3786-13 Tensile strength and elongation, ASTM D5034-09 Tear strength, ASTM D5587-15 Hydrostatic Pressure, AATCC127-2014 Lint Generation, WSP 160.1 (12)		Compatible
Post-Sterilization Biocompatibility Testing	Cytotoxicity ISO 10993-5: 2009	Non-cytotoxic, under the conditions of the test
	Sensitization, ISO 10993-10: 2010	Non-sensitizing, under the conditions of the test
	Irritation, ISO 10993-10:2010	Non-irritating, under the conditions of the test

Summary of Clinical Testing:
Not applicable

Conclusions Drawn from Non-Clinical Data:
Non-clinical data demonstrates that the Cardinal Health™ Sterilization Wrap are as safe, as effective, and performed as well as the legally marketed device identified in this summary.