DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 9, 2017

Cardinal Health 200, LLC
Caroline Miceli
Manager, Regulatory Affairs
1500 Waukegan Road
Waukegan, Illinois 60085

Re: K170762
Trade/Device Name: Cardinal Health™ Non-Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 10, 2017
Received: March 13, 2017

Dear Caroline Miceli:

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" (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 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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170762

Device Name

1. Cardinal Health™ Non-Reinforced Surgical Gown

Indications for Use *(Describe)*

Cardinal Health™ Non-Reinforced Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices; provided sterile and non-sterile.

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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K170762

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Waukegan, IL 60085
www.cardinalhealth.com

510(k) SUMMARY
Cardinal Health™ Non-Reinforced Surgical Gown

Manufacturer:	Cardinal Health 200, LLC 1500 Waukegan Road Waukegan, IL 60085
Regulatory Affairs Contact:	Caroline Miceli 1500 Waukegan Road Waukegan, IL 60085
Telephone Number:	(847) 887-6864
Fax Number:	(847) 785-2461
Date Summary Prepared:	March 10, 2017
Trade Name:	Cardinal Health™ Non-Reinforced Surgical Gown
Regulation Number:	21 CFR §878.4040
Device Class:	Class II
Regulation Name:	Surgical Apparel
Common Name:	Surgical Gown
Product Code:	FYA
Classification Name:	Surgical Gown
Predicate Device:	Convertors® SMS Polyolefin Standard Gown (K020593)

Description

The Cardinal Health™ Non-Reinforced Surgical Gown is a Class II medical device under the FDA product code of FYA, General & Plastic Surgery Panel, and Regulation 21 CFR 878.4040. The device description of the Cardinal Health™ Non-Reinforced Surgical Gown is in accordance with the *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*, issued on August 1, 1993.

The chest front and sleeve critical zones of the Cardinal Health™ Non-Reinforced Surgical Gowns are constructed from a blue polyolefin SMS (spunbond, meltblown, spunbond) and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown. The Cardinal Health™ Non-Reinforced Surgical Gown is a single use, disposable medical device that will be provided in a variety of sterile and non-sterile packaging configurations.

Indications for Use/Intended Use

The Cardinal Health™ Non-Reinforced Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices, provided sterile and non-sterile.

Device and Predicate Device Technical Characteristics

The proposed Cardinal Health™ Non-Reinforced Surgical Gown is substantially equivalent to the predicate Convertors® SMS Polyolefin Standard Gown (K020593) with regards to claims, design, technology, and intended use. Refer to the Side by Side Comparison Table below.

The final proposed finished device was tested in accordance with Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes, August 1993, Guidance for Industry and FDA Staff - Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings issued by the FDA on December 9, 2015 and ANSI/AAMI PB70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Cardinal Health™ Non-Reinforced Surgical Gowns consists of Polyolefin (Polypropylene) SMS nonwoven material including sleeve seams but excluding cuffs, hems, and bindings per AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Drapes Intended for Use in Health care Facilities. Testing was performed on the body and sleeve (equivalent material), sleeve seam, and belt attachment to generate test data shown in the table below. Additional performance testing was performed to further characterize the device.

Side by Side Comparison
Predicate Device: Convertors® SMS Polyolefin Standard Gown
Proposed Device: Cardinal Health™ Non-Reinforced Surgical Gown

Element of Comparison	**Predicate Device:** Convertors® SMS Polyolefin Standard Gown (K020593)	**Proposed Device:** Cardinal Health™ Non-Reinforced Surgical Gown
Intended Use/Indications for Use	Convertors® SMS Polyolefin Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material.	The Cardinal Health™ Non-Reinforced Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices, provided sterile and non-sterile.
Directions for Use	None	Follow your facility protocol.
Material Composition	Polyolefin (Polypropylene) SMS nonwoven	Polyolefin (Polypropylene) SMS nonwoven
Design Features	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab
Sterility	Sterile and non-sterile	Sterile and non-sterile
Use	Single Use; Disposable	Single Use; Disposable
Color	Light Blue	Dark Blue

Element of Comparison	**Predicate Device:**	**Proposed Device:**		
	Convertors® SMS Polyolefin Gown – Standard Gown (K020593)	Cardinal Health™ Non-Reinforced Surgical Gown (Representative Catalog Number 9545)		
	K020593 Test Results	***Test Results (3 Lots)***		***Specification***
		Mean (min/max)		
		Sleeve	Body	
Basis weight (oz/yd^2)				
ASTM D1910-75**	1.6 - 1.8 oz/yd^2	N/A: ASTM D1910-75 replaced by ASTM D3776		
ASTM D3776	N/A: Current Test Method	Mean = 1.32	Mean = 1.32	Target Mean= 1.30
		Ind Min = 1.28	Ind Min = 1.28	Mean Min = 1.20
		Ind Max = 1.36	Ind Max = 1.36	Ind Min = 1.07
Grab tensile, MD* (lbs)				
ASTM D882-83**	25-34 lbs.	N/A: ASTM D882-83 replaced by ASTM D5034		
ASTM D5034	N/A: Current Test Method	Mean = 21.57	Mean = 21.57	N/A
		Ind Min = 18.60	Ind Min = 18.60	
		Ind Max = 23.60	Ind Max = 23.60	
Grab tensile, CD* (lbs)				
ASTM D882-83**	13-20 lbs.	N/A: ASTM D882-83 replaced by ASTM D5034		
ASTM D5034	N/A: Current Test Method	Mean = 13.60	Mean = 13.60	Target Mean = 15.00
		Ind Min = 11.20	Ind Min = 11.20	Mean Min = 11.00
		Ind Max = 16.0	Ind Max = 16.0	Ind Min = 9.50
Trap Tear, MD* (lbs)				
ASTM D5587-15 Highest Peak	3.2-7.4 lbs.	Mean = 3.47	Mean = 3.47	Target Mean = 4.00
		Ind Min = 2.73	Ind Min = 2.73	Mean Min = 2.40
		Ind Max = 4.00	Ind Max = 4.00	Ind Min = 2.00

Element of Comparison	**Predicate Device:**	**Proposed Device:**		
	Convertors® SMS Polyolefin Gown – Standard Gown (K020593)	Cardinal Health™ Non-Reinforced Surgical Gown (Representative Catalog Number 9545)		
	K020593 Test Results	***Test Results (3 Lots)***		***Specification***
		Mean (min/max)		
		Sleeve	Body	
Trap Tear, CD* (lbs)				
ASTM D5587-15 *Highest Peak*	7.0-11.8 lbs.	Mean = 5.63	Mean = 5.63	N/A
		Ind Min = 4.67	Ind Min = 4.67	
		Ind Max = 7.90	Ind Max = 7.90	
Flammability (sec) CPSC, Part 1610	Class I	Class I	Class I	Class I
Alcohol Repellency (rating)				
NWSP 080.8.R0 (15)	>6	Mean = 9	Mean = 9	Target Mean = 7
		Ind Min = 8	Ind Min = 8	Mean Min = 6
		Ind Max = 9	Ind Max = 9	Ind Min = 5
Hydrostatic Head (cm)				
AATCC-127	65-92 cm	Mean = 89.90	Mean = 89.90	Target Mean = 70
		Ind Min = 73.95	Ind Min = 73.95	Mean Min = 60
		Ind Max = 100.98	Ind Max = 100.98	Ind Min = 53
Water Impact (g)				
AATCC-42	0.0-0.10 g	Mean = 0.10	Mean = 0.10	Target Mean = 0.10
		Ind Min = 0.07	Ind Min = 0.07	Mean Max = 0.30
		Ind Max = 0.13	Ind Max = 0.13	Ind Max = 1.0

Note - Individual Maximum (Ind. Max.): specification allows only one value at this level. Individual minimum (Ind. Min.): specification allows only one value at this level. The mean performance of the proposed device was compared to the mean specification values.

* MD Grab tensile not specified, CD Grab tensile is limiting specification value; CD Trap Tear is not specified; MD Trap Tear is the limiting specification value as it is the weaker direction.

** Predicate test methods for basis weight and grab tensile strength were accepted test methods at the time; proposed device was tested on current standards.

Element of Comparison	**Predicate Device:** Convertors® SMS Polyolefin Standard Gown (K020593)	**Proposed Device:** Cardinal Health™ Non-Reinforced Surgical Gown
Liquid Barrier Performance Classification Properties	PB70 Performance Standard was not available at the time of the predicate submission. However, Water Impact and Hydrostatic Head tests were performed and met the equivalent AAMI Level 3 per PB70.	Device was tested in accordance with AAMI PB70:2012 and meets AAMI Level 3 barrier protection requirements for a surgical gown. Testing was performed using 3 lots and 32 samples per lot in each critical zone area. The critical zone areas tested were the body and sleeve (same fabric), the sleeve seam, and front belt attachment.
Biocompatibility	All Materials used in the fabrication of this gown were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 Biological Evaluation of Medical Devices". The biocompatibility test performed were cytotoxicity, sensitization, and irritation/intracutaneous reactivity. These materials have met the requirements of the guidance and were found to be acceptable for the intended use.	Under the conditions of each study, the Cardinal Health™ Non-Reinforced Surgical gown is non-cytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.
Sterilization Modality	Ethylene Oxide (EO)	Ethylene Oxide (EO)

Conclusion Summary

The Cardinal Health™ Non-Reinforced Surgical gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, barrier protection, material composition, and configuration/dimensions. Under the conditions of each study, the Cardinal Health™ Isolation gown is non-cytotoxic, nonirritating, and non-sensitizing per ISO-10993 and have met the requirements of *ANSI/AAMIPB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* for an AAMI Level 3 surgical gown. Therefore, the subject device is determined as safe and as effective for its intended use as the predicate device.

Conclusion Statement

The Cardinal Health™ Non-Reinforced Surgical gowns are as safe, as effective and performs as well as the legally marketed device identified in this submission.