PARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 28, 2016

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

Re: K160339
Trade/Device Name: Cardinal Health Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYC
Dated: June 30, 2016
Received: July 1, 2016

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 yours,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting Division Director
Division of Anesthesiology,
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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) K160339*

Device Name
Cardinal Health™ Isolation Gown

Indications for Use *(Describe)*

Cardinal Health™ Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Cardinal Health™ Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Cardinal Health™ Isolation Gown is a single use, disposable medical device provided 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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510(k) SUMMARY
Cardinal Health™ Isolation 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:	July 25, 2016
Trade Name:	Cardinal Health™ Isolation Gown
Regulation Number:	21 CFR §878.4040
Device Class:	Class II
Regulation Name:	Surgical Apparel
Common Name:	Isolation Gown
Product Code:	FYC
Classification Name:	Surgical Isolation Gown
Predicate Device:	Kool-Gard Procedure/Cover Gown, K952116

Description

The Cardinal Health™ Isolation Gown is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code, FYC. The Cardinal Health™ Isolation Gown is a single use, disposable medical device provided non-sterile. The Cardinal Health™ Isolation Gown is offered in two color (blue and yellow) models and each model is offered in two sizes for a total of four models. Each model is constructed of a nonwoven material and has been tested according to *ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* and meets AAMI Level 3.

Indications for Use/Intended Use

Cardinal Health™ Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Cardinal Health™ Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per *ANSI/AAMI PB70:2012 Liquid BarrierPerformance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* (ANSI/AAMI PB70). The Cardinal Health™ Isolation Gown is a single use, disposable medical device provided non-sterile.

Device and Predicate Device Technical Characteristics

The proposed Cardinal Health™ Isolation Gown is substantially equivalent to the predicate Kool-Gard Procedure/Cover gown with regards to claims, design, technology, and intended use. Refer to the Side by Side Comparison Table below.

The proposed Cardinal Health™ Isolation Gown is constructed of polyolefin (Polypropylene) SMS nonwoven material. The Cardinal Health™ Isolation Gowns consist of a one critical zone throughout the entire gown including seams but excluding cuffs, hems, and bindings and has been tested for barrier performance per ANSI/AAMI PB70:2012. Testing was performed according to the *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes,* issued on August 1, 1993 and *ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.* All results of testing met AATCC-42/AATCC-127, and meets AAMI PB70:2012 Level 3 requirements.

Side by Side Comparison Table
Predicate Device, Kool-Gard Procedure/Cover Gown (K952116)
and Proposed Device, Cardinal Health™ Isolation Gown

Element of Comparison	**Predicate Device:** Kool-Gard® Procedure/Cover Gown (K952116)	**Proposed Device:** Cardinal Health™ Isolation Gown
Intended Use/Indications for Use	The predicate Kool-Gard® Procedure/Cover Gown is intended for non-sterile use only, and is not intended for use in the operation room. It is intended for use in areas where there is potential for light fluid contact. The predicate Kool-Gard® Procedure/Cover Gown is a single use, disposable medical device, provided non-sterile.	Cardinal Health™ Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Cardinal Health™ Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per *ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* (ANSI/AAMI PB70).The Cardinal Health™ Isolation Gown is a single use, disposable medical device provided non-sterile.
Material Composition	Polypropylene SMS nonwoven	Polyolefin (Polypropylene) SMS nonwoven
Design Features	Tape Neck Closure Belt Tie Elastic Cuffs	Medical Tape Neck Closure White Belt Tie Elastic Cuffs
Sterility	Non-Sterile	Non-Sterile
Use	Single Use; Disposable	Single Use; Disposable
Color	Blue, Yellow and White	Blue and Yellow

Element of Comparison	**Predicate Device:** Kool-Gard® Procedure Cover Gown (K952116) Yellow, Blue, White	**Proposed Device:** Cardinal Health™ Isolation Gown Yellow		**Proposed Device:** Cardinal Health™ Isolation Gown Blue	
	K952116 Test Results	***Test Results Mean (min/max)***	***Specification***	***Test Results Mean (min/max)***	***Specification***
Basis weight (oz/yd^2) ASTM D1910-75** ASTM D3776	1 - 1.2 oz/yd^{2***}	N/A Mean = 1.21 Ind Min = 1.19 Ind Max = 1.23	N/A Target Mean= 1.18 Mean min = 1.13 Mean max = 1.25	N/A Mean = 1.18 Ind Min = 1.15 Ind Max = 1.20	N/A Target Mean = 1.18 Mean min = 1.13 Mean max = 1.25
Grab tensile MD* (lb) ASTM D882-83** ASTM D5034	20-22 lb	N/A Mean = 24.38 Ind Min = 21.94 Ind Max = 26.28	N/A N/A	N/A Mean = 22.23 Ind Min = 20.42 Ind Max = 24.03	N/A N/A
Grab tensile CD* (lb) ASTM D882-83** ASTM D5034	10.5 – 13 lb	N/A Mean = 14.54 Ind Min = 12.70 Ind Max = 16.45	N/A Target Mean = 16.00 Mean min = 14.00	N/A Mean = 14.18 Ind Min = 12.40 Ind Max = 15.76	N/A Target Mean= 16.00 Mean min = 14.00
Trap Tear MD, (lbs)* ASTM D5587-15 *Highest Peak*	Performance values not available in predicate 510(k) submission	Mean = 4.74 Ind Min = 3.67 Ind Max = 5.47	Target Mean = 5.40 Mean min = 3.60	Mean = 4.40 Ind Min = 3.26 Ind Max = 5.54	Target Mean = 5.40 Mean min = 3.60

Element of Comparison	**Predicate Device:** Kool-Gard® Procedure Cover Gown (K952116) Yellow, Blue, White	**Proposed Device:** Cardinal Health™ Isolation Gown Yellow		**Proposed Device:** Cardinal Health™ Isolation Gown Blue	
	K952116 Test Results	***Test Results Mean (min/max)***	***Specification***	***Test Results Mean (min/max)***	***Specification***
Trap Tear CD, (lbs)* ASTM D5587-15 *Highest Peak*	Performance values not available in predicate 510(k) submission	Mean = 9.24 Ind Min = 7.54 Ind Max = 12.98	N/A	Mean = 7.99 Ind Min = 6.64 Ind Max = 11.11	N/A
Flammability CPSC, Part 1610	Performance values not available in predicate 510(k) submission	Class I	Class I	Class I	Class I
Hydrostatic Head (cm) AATCC 127	Performance values not available in predicate 510(k) submission	Body/Sleeve: Mean = 69 Ind Min = 56 Ind Max = 84	Target Mean = 67 Mean min = 55 Ind Min = 52	Body/Sleeve: Mean = 72 Ind Min = 53 Ind Max = 80	Target Mean = 67 Mean min = 55 Ind Min = 52
Water Impact (g) AATCC-42 (performed with simulated blood) AATCC-42 (performed with water per AATCC-42:2013)	4.4 g	N/A Body/Sleeve: Mean = 0.08 Ind Min = 0.05 Ind Max = 0.13	N/A Target Mean = 0.10 Max = 0.5 Ind Max = 1.0	N/A Body/Sleeve: Mean = 0.08 Ind Min = 0.04 Ind Max = 0.13	N/A Target Mean = 0.10 Max = 0.5 Ind Max = 1.0

Element of Comparison	**Predicate Device:** Kool-Gard® Procedure Cover Gown (K952116) Yellow, Blue, White	**Proposed Device:** Cardinal Health™ Isolation Gown Yellow		**Proposed Device:** Cardinal Health™ Isolation Gown Blue	
	K952116 Test Results	***Test Results Mean (min/max)***	***Specification***	***Test Results Mean (min/max)***	***Specification***
Liquid Barrier Performance Classification Properties	Predicate Device: PB70 Performance standard not available at time of predicate submission.	Device was tested in accordance with ANSI/AAMI PB70:2012 and meets Level 3 requirements for an isolation gown. The critical zone areas tested were the body and sleeve (same fabric), the sleeve seam, front belt or tie attachment, and the front seam arm attachment using multiple lots.			
Biocompatibility	Predicate Device: Biocompatibility was accepted based on a material equivalency statement that is included in the predicate submission.	Under the conditions of each study, the Cardinal Health™ Isolation gown is non-cytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.			
Sterilization Modality	None (Non-Sterile)	None (Non-Sterile)			

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.

*** The basis weight for the predicate device was reported as 1 - 1.2 oz/yd^2 which converts to 34 - 41 gsm.

The Cardinal Health™ Isolation gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, material composition, and configuration/dimensions. Under the conditions of each study, the Cardinal Health™ Isolation gown is non-cytotoxic, non-irritating, and non-sensitizing per ISO-10993 and have met the requirements of *ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities* for an AAMI Level 3 isolation gown. Therefore, the subject device is determined as safe and effective for it's intended use as the predicate device.

Conclusion:

The Cardinal Health™ Isolation Gowns are as safe, as effective and performs as well as the legally marketed device identified in this submission.