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

May 12, 2016

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

Re: K153316
Trade/Device Name: Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: April 15, 2016
Received: April 18, 2016

Dear Ms. Megan 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" (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,

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

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)*

K153316

Device Name

Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)

Indications for Use *(Describe)*

A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time, 0.01 μg/cm^2/minute
1.	Carmustine (BCNU) (3.3 mg/ml)	60.1
2.	Cisplastin, (1.0 mg/ml)	>240
3.	Cyclophosphamide (20 mg/ml)	>240
4.	Doxorubicin HCl (2.0 mg/ml)	>240
5.	Etoposide (Toposar) (20 mg/ml)	>240
6.	Fluorouracil (50 mg/ml)	>240
7.	Methotrexate (25 mg/ml)	>240
8.	Mitomycin C (0.5 mg/ml)	>240
9.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
10.	Thiotepa (10 mg/ml)	110.5
11.	Vincristine Sulfate(1 mg/ml)	>240

CAUTION: Testing showed an average breakthrough time of 60.1 minutes with Carmustine

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

K153316

Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)

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:	April 15, 2016

Product Trade Name:	Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow)
Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Panel:	General and Plastic Surgery
Regulation:	21 CFR 878.4460
Product Code:	KGO
Subsequent Product Code:	LZC

Predicate Devices:	K113707 - Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating Tested for Use with Chemotherapy Drugs
Reason for 510(k) Submission:	New device
Device Description:	The proposed device is a disposable device. It is not made with natural rubber latex. Instead, the gloves are formulated using neoprene synthetic polymer and are coated with nitrile coating and is yellow in color. The glove are manufactured using molds that feature anti-slip finish, independent thumb and mechanically locking cuffs to help prevent cuff roll down. They are offered powder-free and sterile. This glove is for single use only.
Intended Use:	A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Table 1: Chemotherapy Drug Permeation Time

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time, 0.01 μg/cm²/minute
1.	Carmustine (BCNU) (3.3 mg/ml)	60.1
2.	Cisplastin, (1.0 mg/ml)	>240
3.	Cyclophosphamide (20 mg/ml)	>240
4.	Doxorubicin HCl (2.0 mg/ml)	>240
5.	Etoposide (Toposar) (20 mg/ml)	>240
6.	Fluorouracil (50 mg/ml)	>240
7.	Methotrexate (25 mg/ml)	>240
8.	Mitomycin C (0.5 mg/ml)	>240
9.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
10.	Thiotepa (10 mg/ml)	110.5
11.	Vincristine Sulfate (1 mg/ml)	>240

CAUTION: Testing showed an average breakthrough time of 60.1 minutes with Carmustine

Substantial Equivalence: The proposed device is substantially equivalent to the predicate device identified in this 510(k) summary. Substantial equivalence can be established in regard to intended use, physical properties and characteristics, design and product features. Both gloves are made of synthetic neoprene using similar manufacturing process.

Table 2: Summary of Technological Characteristics

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**New Device** Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow) (K153316)	**Predicate Device** Sterile Neoprene Powder-Free Surgical Glove w/Chemo Claim (K113707)
Material Composition	Synthetic Neoprene Polymer coated with Nitrile	Synthetic Neoprene Polymer coated with Nitrile
Design	Hand Specific Independent Thumb Beaded Cuff Lubricated	Hand Specific Independent Thumb Beaded Cuff Lubricated
Intended Use	A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	These powder-free sterile light brown colored surgeon's gloves are a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
Indications for Use	In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Label Claims	Sterile Powder-free Neoprene Surgical Glove with Nitrile Coating Not made with natural rubber latex For Single Use Only Tested for Use with Chemotherapy Drugs AQL 0.65	Sterile Powder-free Neoprene Surgical Glove with Nitrile Coating Not made with natural rubber latex For Single Use Only Tested for Use with Chemotherapy Drugs AQL 1.0
Dimensions & Physical Properties	Meets ASTM D3577	Meets ASTM D3577
Freedom from Holes	Meets 21CFR 800.20 & ASTM D3577 requirements of AQL 1.5	Meets 21CFR 800.20 & ASTM D3577 requirements of AQL 1.5
Powder Residual	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577
Biocompatibility (Irritation, ISO 10993-0:2010; Sensitization, ISO 10993-10: 2010)	Non-Irritating, under the conditions of the study Non-sensitizing, under the conditions of the study	Non-Irritating, under the conditions of the study Non-sensitizing, under the conditions of the study

Table 3: Summary of Non-Clinical Tests

PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Biocompatibility:		
Primary Skin Irritation	ISO 10993-10	Non-Irritating, under the conditions of the study
Guinea Pig Maximization	ISO 10993-10	Non-sensitizing, under the conditions of the study
Physical Characteristics:		
Dimensions	ASTM D3577	Meets requirements
Physical Properties	ASTM D3577	Meet requirements for synthetic surgical gloves
Freedom from Holes	21 CFR 800.20 & ASTM D3577	Tested in accordance with ASTM D 5151 and meets 21CFR 800.20 & ASTM D3577 requirements of AQL 1.5
Powder Residual	ASTM D3577 tested using ASTM standard D6124	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577. Results generated values < 2mg of residual powder per glove.
Chemotherapy Drug Permeation	ASTM D 6978	Gloves were tested using ASTM D6978. Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the chemotherapy drugs tested exceeded the maximum testing time of 240 minutes except for Carmustine (BCNU) (3.3 mg/ml), which showed permeation time of 60.1 minutes, and Thiotepa (10 mg/ml), which showed permeation time of 110.5 minutes.

Table 4: Summary of Comparative Performance

Comparative Performance Information Summary			
Characteristic	**Requirement**	**New Device**	**Predicate Device**
Biocompatibility:	ISO 10993-1	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Non-Irritating, under the conditions of the study	Non-Irritating, under the conditions of the study
Guinea Pig Maximization	ISO 10993-10	Non-sensitizing, under the conditions of the study	Non-sensitizing, under the conditions of the study
Dimensions	ASTM D3577	Meets requirements	Meets requirements
Physical Properties	ASTM D3577	Meets requirements	Meets requirements
Freedom from Holes	21CFR800.20, ASTM D3577	Meets requirements	Meets requirements
Powder Residual	ASTM D3577	Meets requirements	Meets requirements
Chemotherapy Drug Permeation	ASTM D6978	Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the 11 chemotherapy drugs tested exceeded the maximum testing time of 240 minutes except for Carmustine (BCNU) (3.3 mg/ml), which showed permeation time of 60.1 minutes, and Thiotepa (10 mg/ml), which showed permeation time of 110.5 minutes.	Under the test conditions prescribed by the test, the minimum normalized breakthrough detection times for each of the 10 chemotherapy drugs tested exceeded the maximum testing time of 240 minutes except for Carmustine (BCNU) (3.3 mg/ml), which showed permeation time of 0.20 minutes, and Thiotepa (10 mg/ml), which showed permeation time of 82.2 minutes.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION			
Clinical data is not required.			
CONCLUSIONS DRAWN FROM NON-CLINICAL DATA			
Non-clinical data demonstrates Cardinal Health™ Sterile Neoprene Powder-free Surgical Gloves with Nitrile Coating and Tested for Use with Chemotherapy Drugs (Yellow) meet the technological characteristics of ASTM D3577 standard, and are as safe, as effective, and performed as well as the legally marketed devices identified in this summary.			