



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

June 15, 2017

Cardinal Health, Inc.
Tatyana Bogdan
Director, Global Regulatory Affairs
1500 Waukegan Road
Waukegan, Illinois 60085

Re: K170198

Trade/Device Name: Cardinal Health Sterile Polyisoprene Blend Powder-Free Surgical
Gloves, Tested for Use with Chemotherapy Drugs (White)

Regulation Number: 21 CFR 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: Class I

Product Code: KGO

Dated: May 15, 2017

Received: May 16, 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" (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

Indications for Use

510(k) Number (if known)

K170198

Device Name

Cardinal Health™ Sterile Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White)

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)	17.9
2.	Cisplatin, (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.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
9.	Thiotepa (10 mg/ml)	40.3
10.	Vincristine Sulfate (1.0 mg/ml)	>240

WARNING: Do not use with Carmustine (BCNU) (3.3 mg/ml)

CAUTION: Testing showed an average breakthrough time of 40.3 minutes with Thiotepa (10 mg/ml).

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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K170198

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K170198 510(k) SUMMARY

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Cardinal Health™ Sterile Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White)

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) 887-2325

Fax Number: (847) 887-2461

Date Summary Prepared: June 5, 2017

Product Trade Name: Cardinal Health™ Sterile Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White)

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: Cardinal Health™ Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs, previously cleared under K110272 on June 08, 2011

**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 polyisoprene and neoprene, which are synthetic rubber latex.

The gloves 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)	17.9
2.	Cisplatin, (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.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
9.	Thiotepa (10 mg/ml)	40.3
10.	Vincristine Sulfate (1.0 mg/ml)	>240

WARNING: Do not use with Carmustine (BCNU) (3.3 mg/ml)

CAUTION: Testing showed an average breakthrough time of 40.3 minutes with Thiotepa (10 mg/ml).

Substantial Equivalence:

Cardinal Health™ Sterile Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White), are substantially equivalent to Cardinal Health™ Sterile Polyisoprene Powder-Free Surgical Gloves in regard to intended use, sizes, physical characteristics, design, manufacturing process and product features.

Table 2: Summary of Technological Characteristics

Summary of the technological characteristics of the device compared to the predicate devices		
Characteristic	New Device Cardinal Health™ Sterile Polyisoprene Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White)	Predicate Device Cardinal Health™ Sterile Polyisoprene Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (K110272)
Material Composition	Synthetic rubber blend of polyisoprene and neoprene	Synthetic Polyisoprene
Design	Hand Specific Independent Thumb Beaded Cuff Lubricated	Hand Specific Independent Thumb Beaded Cuff Lubricated
Intended Use / Indication for 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.	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.
Label Claims	Sterile Powder-free Not made with natural rubber latex Single Use Only Tested for Use with Chemotherapy Drugs AQL 0.65 (Freedom from Holes per ASTM D5151)	Sterile Powder-free Not made with natural rubber latex Single Use Only Tested for Use with Chemotherapy Drugs AQL 0.65 (Freedom from Holes per ASTM D5151)
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 10993-10:2010; 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 Comparative Performance

Comparative Performance Information Summary			
Characteristic	Requirement	New Device Cardinal Health™ Sterile Polyisoprene Blend Powder-Free Surgical Gloves, tested for Use with Chemotherapy Drugs (White)	Predicate Device Cardinal Health™ Sterile Polyisoprene Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (K110272)
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
Chemotherapy Drug Permeation	ASTM D6978	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 17.9 minutes, and Thiotepe (10 mg/ml), which showed permeation time of 40.3 minutes.	Gloves were tested using ASTM D6978.
Powder Residual	ASTM D3577	Meets requirements	Meets requirements

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 Polyisoprene Blend Powder-Free Surgical Gloves, Tested for Use with Chemotherapy Drugs (White), meet the technological characteristics of ASTM D3577 standard, and are as safe, as effective, and performs as well as the legally marketed device identified in this summary.