DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 11, 2016

Cardinal Health, Inc.
Ms. Megan Middaugh
Manager, Regulatory Affairs
1500 Waukegan Rd
Waukegan, IL 60085

Re: K160875
Trade/Device Name: Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: June 9, 2016
Received: June 13, 2016

Dear Ms. 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)*
K160875

Device Name
Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating

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.

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
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Waukegan, IL 60085
cardinalhealth.com

510(k) SUMMARY

Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating

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:	June 9, 2016

Product Trade Name:	Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
Common Name:	Orthopedic Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Panel:	General and Plastic Surgery
Regulation:	21 CFR 878.4460
Product Code:	KGO

510(K) SUMMARY (CONT'D)

Predicate Devices:

1) Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves previously cleared under K092304 on September 15, 2009

2) Sterile Latex Powder-Free Surgical Orthopedic Gloves with Hydrogel Coating cleared under K151778 on March 24, 2016

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, which is a synthetic rubber latex, and is brown in color. The glove is coated with hydrogel polymer coating.

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.

This glove is suitable for use as a specialty surgical glove intended for orthopedic procedures or other procedures where a thicker barrier may be desired such as trauma and reconstructive surgery

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.

Substantial Equivalence:

Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating are substantially equivalent to Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves and the Sterile Latex Powder-Free Surgical Orthopedic Gloves with Hydrogel Coating in regards to intended use, sizes, physical characteristics, design and product features. All three gloves are intended for use as specialty orthopedic surgeon's gloves.

Table 1: 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 Orthopedic Surgical Gloves with Hydrogel Coating	**Predicate Device** Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves (K092304)	**Predicate Device** Sterile Latex Powder-Free Surgical Orthopedic Gloves with Hydrogel Coating (K151778)
Material Composition	Synthetic Polyisoprene coated with Hydrogel polymer	Synthetic Polyisoprene	Natural Rubber Latex coated with Hydrogel
Design	Hand Specific Independent Thumb Beaded Cuff Lubricated Polymer Coating	Hand Specific Independent Thumb Beaded Cuff Lubricated	Hand Specific Independent Thumb Beaded Cuff Lubricated Polymer Coating
Intended Use / Indication for Use	Powder-Free Orthopedic Surgeon's Glove	Powder-Free Orthopedic Surgeon's Glove	Powder-Free Orthopedic Surgeon's Glove
Label Claims	Sterile Powder-free Polyisoprene Surgical Glove with Hydrogel Coating Not made with natural rubber latex Single Use Only Orthopedic AQL 0.65 (Freedom from Holes per ASTM D5151)	Sterile Powder-free Not made with natural rubber latex For Single Use Only Orthopedic	Sterile Powder-free Latex Surgical Glove with Hydrogel Coating Single Use Only Orthopedic AQL 0.65 (Freedom from Holes per ASTM D5151)
Dimensions & Physical Properties	Meets ASTM D3577	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	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	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	Non-Irritating, under the conditions of the study Non-sensitizing, under the conditions of the study

Table 2: 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.

Table 3: Summary of Comparative Performance

Comparative Performance Information Summary				
Characteristic	**Requirement**	**New Device** Cardinal Health™ Sterile Polyisoprene Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating	**Predicate Device** Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves (K092304)	**Predicate Device** Sterile Latex Powder-Free Surgical Orthopedic Gloves with Hydrogel Coating (K151778)
Biocompatibility:	ISO 10993-1	Meets requirements	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	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	Non-sensitizing, under the conditions of the study
Dimensions	ASTM D3577	Meets requirements	Meets requirements	Meets requirements
Physical Properties	ASTM D3577	Meets requirements	Meets requirements	Meets requirements
Freedom from Holes	21CFR800.20, ASTM D3577	Meets requirements	Meets requirements	Meets requirements
Powder Residual	ASTM D3577	Meets requirements	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 Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating meet the technological characteristics of ASTM D3577 standard, and are as safe, as effective, and performs as well as the legally marketed devices identified in this summary.