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

March 24, 2016

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

Re: K151778
Trade/Device Name: Cardinal Health™ Sterile Latex 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: February 18, 2016
Received: February 22, 2016

Dear Ms. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith, M.S.
Division 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)*
K151778

Device Name
Cardinal Health TM Sterile Latex Powder-Free Orthopedic Surgical Gloves With Hydrogel Coating

Indications for Use *(Describe)*

A surgeon's glove is a device made of natural 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

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) 887-2461

Date Summary Prepared: March 23, 2016

Product Trade Name: Cardinal Health™ Sterile Latex 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 OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

Predicate Devices:	K111015 – Protexis™ Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating K903987- Triflex™ Orthopedic Sterile Surgeon's Glove
Reason for 510(k) Submission:	New device
Device Description:	The proposed device is a sterile latex powder-free surgical glove that is formulated using natural rubber latex and is brown in color. The glove is coated with hydrogel polymer coating. The glove is manufactured using molds that feature an 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 surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
Substantial Equivalence:	The proposed device is substantially equivalent to the predicate devices identified in this 510(k) summary. Substantial equivalence can be established in regard to intended use, physical properties and characteristics, design and product features. All gloves are made of natural rubber latex using similar manufacturing processes.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

Performance Data

	New Device Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating (K151778)	**Predicate Device 1** Protexis™ Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating (K111015)	**Predicate Device 2** Triflex™ Orthopedic Sterile Surgeon's Glove (K903987)
Characteristic	Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating	Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating	Orthopedic Sterile Latex Powdered Surgeon's Glove
Material Composition	Natural Rubber Latex	Natural Rubber Latex	Natural Rubber Latex
Design	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated Hydrogel Polymer Coating	Single Use Sterile Powder-free Hand Specific Independent Thumb Beaded Cuff Lubricated Hydrogel Polymer Coating	Single Use Sterile Powdered Hand Specific Independent Thumb Beaded Cuff
Label Claim	• Latex • Single Use • Sterile • Powder-free • Hydrogel Coating • Contains less than 50 µg/dm^2 of total water extractable protein per glove • Puncture Resistance $\geq$ 5N	• Latex • Single Use • Sterile • Powder-free • Hydrogel Coating • Contains less than 50 µg/dm^2 of total water extractable protein per glove	• Latex • Single Use • Sterile • Powdered

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

	New Device Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating (K151778)	**Predicate Device 1** Protexis™ Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating (K111015)	**Predicate Device 2** Triflex™ Orthopedic Sterile Surgeon's Glove (K903987)
Intended Use/ Indications for Use	Orthopedic Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove	Orthopedic Powdered Surgeon's Glove
Dimensions & Physical Properties	Meets ASTM D3577	Meets ASTM D3577	Meets ASTM D3577
Freedom from Holes	AQL meets 21CFR 800.20 & ASTM D3577 requirements	AQL meets 21CFR 800.20 & ASTM D3577 requirements	AQL meets 21CFR 800.20 & ASTM D3577 requirements
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	N/A
Protein Contents	Contains less than 50 µg/dm^2 of total water extractable protein per glove as tested per ASTM D5712	Contains less than 50 µg/dm^2 of total water extractable protein per glove as tested per ASTM D5712	N/A
Puncture Resistance	Puncture Resistance ≥ 5N as tested per AS/NZ 4179	N/A	N/A

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence

Performance Test Summary-New Device

Characteristics	Standard/Test/FDA Guidance	Results Summary
Biocompatibility:		
Primary Skin Irritation	ISO 10993-10	Under conditions of the study, gloves are non-irritating.
Guinea Pig Maximization	ISO 10993-10	Under the conditions of the study, gloves do not display any potential for sensitization.
Physical Characteristics:		
Dimensions	ASTM D3577	Meet requirements
Physical Properties	ASTM D3577	Meet requirements for rubber surgical gloves
Freedom from Holes	21 CFR 800.20 & ASTM D3577	Tested in accordance with ASTM D5151 with acceptable results
Powder Residual	ASTM D3577 tested using ASTM standard D6124	Gloves meet powder level requirements for "Powder-Free" designation. Results generated values < 2mg of residual powder per glove.
Protein Content	FDA Medical Glove Guidance Manual, ASTM D5712	Gloves yielded the results of less than 50 µg/dm^2 of total water extractable protein per glove.
Puncture Resistance	AS/NZ 4179	Tested in accordance with AS/NZ with acceptable results

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

Comparative Performance Information Summary

Characteristic	**Requirement**	**New Device** Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating (K151778)	**Predicate Device 1** Protexis™ Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating (K111015)	**Predicate Device 2** Triflex™ Orthopedic Sterile Surgeon's Glove (K903987)
Biocompatibility	ISO 10993-1	Meets requirements	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Pass	Pass	Pass
Guinea Pig Maximization	ISO 10993-10	Pass	Pass	Pass
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	N/A
Protein Content	ASTM D5712	Pass	Pass	N/A
Puncture Resistance	AZ/NZ 4179	Pass	N/A	N/A

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating
K151778

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or Clinical Information:

Clinical Data is not required.

Conclusions Drawn from Non-Clinical Data:

Non-clinical data demonstrates that the Cardinal Health™ Sterile Latex Powder-Free Orthopedic Surgical Gloves with Hydrogel Coating meet the technological characteristics of the ASTM D3577 standard. These gloves are as safe and as effective and performs as well as the legally marketed devices identified in this submission.