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

July 25, 2016

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

Re: K160411
Trade/Device Name: Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu-Thera® Coating (Esteem® Synthetic with Neu-Thera®)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 13, 2016
Received: June 14, 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)*
K160411

Device Name
Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu- thera® Coating (Esteem® Synthetic with Neu-Thera®)

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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

Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu-thera® Coating (Esteem® Synthetic with Neu-Thera®)

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: July 14, 2016

Product Trade Name: Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu-Thera® Coating (Esteem® Synthetic with Neu-Thera®)

Common Name: Examination Gloves

Classification Name: Patient Examination Gloves

Classification Panel: General Hospital and Personal Use Devices

Regulation: 21 CFR 880.6250

Product Code: LYZ

510(K) SUMMARY (CONT'D)

Predicate Devices:	K052568 - Cardinal Health's Esteem Stretchy Synthetic with Neu-Thera® Powder-Free Exam Gloves
Reason for 510(k) Submission:	Modification of a legally marketed device
Device Description:	The proposed device is a disposable device intended for over the counter use. It is not made with natural rubber latex. Instead, the gloves are formulated using vinyl synthetic polymer. The glove is coated with an emollient coating. The gloves are manufactured using molds that are ambidextrous. They are offered powder-free and non-sterile.
Intended Use:	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
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 vinyl using the same manufacturing process.

Table 1: Summary of Technological Characteristics

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	**Subject Device** Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu-Thera® Coating (Esteem® Synthetic with Neu-Thera®)	**Predicate Device** Cardinal Health's Esteem Stretchy Synthetic with Neu-Thera® Powder-Free Exam Gloves (K052568)
Material Composition	Vinyl Coated with emollient coating	Vinyl Coated with emollient coating
Design	Ambidextrous Beaded cuff Lubricated	Ambidextrous Beaded cuff Lubricated
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Label Claims	Single Use Only Non-sterile Powder-free Not made with natural rubber latex Coated with proprietary formulation	Single Use Only Non-sterile Powder-free Not made with natural rubber latex Coated with proprietary formulation
Dimensions & Physical Properties	Meets ASTM D5250	Meets ASTM D5250
Freedom from Holes	Meets 21CFR 800.20 & ASTM D5250 requirements of AQL 2.5	Meets 21CFR 800.20 & ASTM D5250 requirements of AQL 2.5
Powder Residual	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D5250	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D5250

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
Guinea Pig Maximization	ISO 10993-10	Non-sensitizing
Physical Characteristics:		
Dimensions	ASTM D5250	Meets requirements
Physical Properties	ASTM D5250	Meet requirements for vinyl examination gloves
Freedom from Holes	21 CFR 800.20 & ASTM D5250	Tested in accordance with ASTM D 5151 with acceptable results; Meets requirements of AQL 2.5
Powder Residual	ASTM D5250 tested using ASTM standard D6124	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D5250. Results generated values < 2mg of residual powder per glove.

Table 3: Summary of Comparative Performance

Comparative Performance Information Summary			
Characteristic	**Requirement**	**Subject Device** Cardinal Health™ Vinyl Powder-Free Exam Gloves with Neu-Thera® Coating (Esteem® Synthetic with Neu-Thera®)	**Predicate Device** Cardinal Health's Esteem Stretchy Synthetic with Neu-Thera® Powder-Free Exam Gloves (K052568)
Biocompatibility:	ISO 10993-1	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Non-irritating	Non-irritating
Guinea Pig Maximization	ISO 10993-10	Non-sensitizing	Non-sensitizing
Dimensions	ASTM D5250	Meets requirements	Meets requirements
Physical Properties	ASTM D5250	Meets requirements	Meets requirements
Freedom from Holes	21CFR800.20, ASTM D5250	Meets requirements	Meets requirements
Powder Residual	ASTM D5250	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™ Vinyl Powder-Free Exam Gloves with Neu-Thera® Coating (Esteem® Synthetic with Neu-Thera®) meet the technological characteristics of ASTM D5250 standard, and are as safe, as effective, and performed as well as the legally marketed devices identified in this summary.