January 14, 2026

Cardinal Health
Vani Bala
Senior Regulatory Affairs Specialist
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K252313
Trade/Device Name: Cardinal Health Nitrile Examination Gloves Extended Cuff
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: December 17, 2025
Received: December 19, 2025

Dear Vani Bala:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. K252313 ?

Please provide the device trade name(s). ?

Cardinal Health Nitrile Examination Gloves Extended Cuff

Please provide your Indications for Use below. ?

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The gloves was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978, “Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs".

The following drugs have been tested with these gloves:

Chemotherapy Drug & Concentration	Minimum Breakthrough Detection Time in Minutes, 0.01 µg/cm2/min:
Bendamustine HCl, 5 mg/ml (5,000 ppm)	>240 min
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	>240 min
Busulfan, 6 mg/ml (6,000 ppm)	>240 min
Carboplatin, 10 mg/ml (10,000 ppm)	>240 min
Carmustine 3.3 mg/ml (3,300 ppm)	10.0 min
Chloroquine, 50 mg/ml (50,000 ppm)	>240 min
Cisplatin, 1mg/ml (1000 ppm)	>240 min
Cyclophosphamide 20mg/ml (20,000 ppm)	>240 min
Cytarabine HCl (Cytosine), 100 mg/ml (100,000 ppm)	>240 min
Dacarbazine (DTIC), 10 mg/ml (10,000 ppm)	>240 min
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240 min
Epirubicin HCl, 2 mg/ml (2,000 ppm)	>240 min
Etoposide, 20 mg/ml (20,000 ppm)	>240 min
Fludarabine, 25 mg/ml (25,000 ppm)	>240 min
Fluorouracil (5 Flu), 50mg/ml (50,000ppm)	>240 min
Gemcitabine HCl, 38 mg/ml (38,000 ppm)	>240 min
Idarubicin HCl, 1 mg/ml (1,000 ppm)	>240 min
Ifosfamide (IFEX), 50 mg/ml (50,000 ppm)	80.0 min
Mechlorethamine HCl, 1 mg/ml (1,000 ppm)	>240 min
Melphalan HCl, 5 mg/ml (5,000 ppm)	>240 min
Methotrexate, 25mg/ml (25,000ppm)	>240 min
Mitomycin C, 0.5mg/ml (500 ppm)	>240 min
Mitoxantrone HCl (2.0 mg/mL) (2000 ppm)	>240 min
Oxaliplatin, 5 mg/ml (5,000 ppm)	>240 min
Paclitaxel, 6mg/ml (6,000ppm)	>240 min
Rituximab, 10 mg/ml (10,000 ppm)	>240 min
Thiotepa, l0mg/ml (10,000ppm)	20.0 min
Trisenox (Arsenic Trioxide), 1 mg/ml (1,000 ppm)	>240 min
Vincristine sulfate, 1mg/ml (1000 ppm)	>240 min
Vinorelbine, 10 mg/ml (10,00 ppm)	>240 min

Opioid Drug	Minimum Breakthrough Detection Time in Minutes, 0.01 µg/cm2/min:
Fentanyl Citrate Injection, 100mcg/2mg	>240 min

*Please note that the following drugs have low permeation times:
Carmustine: 10.0 minutes, Thiotepa: 20.0 minutes
Warning: Do not use with Carmustine & Thiotepa.
Caution: Testing showed breakthrough time of 80.0 minutes with Ifosfamide IFEX (50.0 mg/mL).

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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