August 28, 2021

Cardinal Health 200, LLC
William Cisneros
Sr. Regulatory Affairs Specialist
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K211390
Trade/Device Name: Nitrile Blue Powder-free Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: July 30, 2021
Received: August 3, 2021

Dear William Cisneros:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For Clarence W. Murray III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211390

Device Name
Nitrile Blue Powder-Free Examination Gloves

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. In addition, these gloves have been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, “Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."

Chemotherapy Drug Permeation Resistance (minimum breakthrough detection time in minutes, 0.01 µg/cm2/min):

1. Azacitidine (Vidaza) ..... (25 mg/ml) ≥ 240
2. Bendamustine ..... (5 mg/ml) ≥ 240
3. Bleomycin ..... (15 mg/ml) ≥ 240
4. Bortezomib (Velcade) ..... (1 mg/ml) ≥ 240
5. Busulfan ..... (6 mg/ml) ≥ 240
6. Carboplatin ..... (10 mg/ml) ≥ 240
7. Carfilzomib..... (2 mg/ml) ≥ 240
8. Carmustine BCNU ..... (3.3 mg/ml) 14.7 (Do not use)
9. Cetuximab (Erbitux) ..... (2 mg/ml) ≥ 240
10. Cisplatin ..... (1.0 mg/ml) ≥ 240
11. Cyclophosphamide (Cytoxan) ..... (20 mg/ml) ≥ 240
12. Cytarabine HCl (Cytosine) ..... (100 mg/ml) ≥ 240
13. Cytovene ..... (10 mg/ml) ≥ 240
14. Dacarbazine DTIC ..... (10 mg/ml) ≥ 240
15. Daunorubicin ..... (5.0 mg/ml) ≥ 240
16. Decitabine ..... (5 mg/ml) ≥ 240
17. Docetaxel ..... (10.0 mg/ml) ≥ 240
18. Doxorubicin Hydrochloride ..... (2.0 mg/ml) ≥ 240
19. Ellence (Epirubicin) ..... (2 mg/ml) ≥ 240
20. Eribulin Mesylate ..... (0.5 mg/ml) ≥ 240
21. Etopside Toposar ..... (20 mg/ml) ≥ 240
22. Fludarabine ..... (25 mg/ml) ≥ 240
23. Fluorouracil (5-Fluorouracil / Adrucil) ..... (50mg/ml) ≥ 240
24. Fulvestrant ..... (50 mg/ml) ≥ 240
25. Gemcitabine ..... (38.0 mg/ml) ≥ 240
26. Idarubicin ..... (1.0 mg/ml) ≥ 240
27. Ifosfamide ..... (50.0 mg/ml) ≥ 240
28. Irinotecan HCl ..... (20.0 mg/ml) ≥ 240
29. Mechlorethamine HCl ..... (1.0 mg/ml) ≥ 240
30. Melphalan ..... (5 mg/ml) ≥ 240
31. Methotrexate ..... (25 mg/ml) ≥ 240
32. Mitomycin-C ..... (0.5 mg/ml) ≥ 240
33. Mitoxantrone ..... (2.0 mg/ml) ≥ 240
34. Oxaliplatin ..... (5 mg/ml) ≥ 240
35. Paclitaxel (Taxol) ..... (6 mg/ml) ≥ 240
36. Pemetrexed ..... (25 mg/ml) ≥ 240

37. Pertuzumab ..... (30 mg/ml) ≥ 240
38. Raltitrexed ..... (0.5 mg/ml) ≥ 240
39. Retrovir ..... (10 mg/ml) ≥ 240
40. Rituximab ..... (10 mg/ml) ≥ 240
41. Temsirolimus ..... (25 mg/ml) ≥ 240
42. Thiotepa ..... (10 mg/ml) 39.4 (Do not use)
43. Topotecan HCL ..... (1 mg/ml) ≥ 240
44. Trastuzumab ..... (21 mg/ml) ≥ 240
45. Triclosan ..... (1 mg/ml) ≥ 240
46. Trisenox (Arsenic Trioxide) ..... (1 mg/ml) ≥ 240
47. Vinblastine ..... (1 mg/ml) ≥ 240
48. Vincristine Sulfate ..... (1.0 mg/ml) ≥ 240
49. Vinorelbine ..... (10 mg/ml) ≥ 240
50. Zoledronic Acid ..... (0.8 mg/ml) ≥ 240

The maximum testing time is 240 minutes. Please note that Carmustine (BCNU) (3.3 mg/ml) and Thiotepa (10 mg/ml) have extremely low permeation times and should not be used with this glove.

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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