Medline Industries, Inc.
Adam Ostrower
Regulatory Affairs Sr. Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K200960
Trade/Device Name: Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 7, 2020
Received: April 10, 2020

Dear Mr. Ostrower:

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 and Part 809); 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,

Elizabeth F. Claverie, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200960

Device Name
Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)

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

Summarized in Table 1 below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough time
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	12.4 minutes
Cisplatin	1.0 mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	>240 minutes
Fluorouracil	50.0 mg/ ml (50,000 ppm)	>240 minutes
Methotrexate	25 mg/ml (25,000 ppm)	>240 minutes
Mitomycin C	0.5 mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	>240 minutes
ThioTepa	10.0 mg/ml (10,000 ppm)	27.4 minutes
Vincristine Sulfate (Oncovin)	1.0 mg/ml (1,000 ppm)	>240 minutes

Do Not Use with Carmustine or Thiotepa

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.

510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Adam Ostrower
Regulatory Affairs Sr. Specialist
Phone: 224-931-1513
Email: aostrower@medline.com

Summary Preparation Date
July 10th, 2020

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)
Common Name: Non-powdered patient examination glove
Classification Name: Medical Gloves with Chemotherapy Labeling Claims – Test For Use with Chemotherapy Drugs
Product Code: LZA. LZC
Classification Panel: General Hospital
Regulatory Class: Class I
Regulation Number: 21 CFR 880.6250

Predicate Device
Medline Powder Free Blue Nitrile Examination Glove (Tested for use with Chemotherapy Drugs)
K051378

Device Description
The Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy drugs) are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are dark blue, powder free, nitrile ambidextrous gloves with a beaded cuff. The gloves are offered in sizes small, medium, large, extra large, and extra extra large packaged in a chipboard box.

The gloves are designed and manufactured in accordance with the ASTM D6319-10 standard and are tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013).

Indications for Use

The Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy drugs) are a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Summarized in Table 1 below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough time
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	12.4 minutes
Cisplatin	1.0 mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	>240 minutes
Fluorouracil	50.0 mg/ml (50,000 ppm)	>240 minutes
Methotrexate	25 mg/ml (25,000 ppm)	>240 minutes
Mitomycin C	0.5 mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	>240 minutes
ThioTepa	10.0 mg/ml (10,000 ppm)	27.4 minutes
Vincristine Sulfate (Oncovin)	1.0 mg/ml (1,000 ppm)	>240 minutes

Do Not Use with Carmustine or Thiotepa

Summary of Technological Characteristics

Table 2: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)	Medline Powder Free Blue Nitrile Examination Glove (Tested for use with Chemotherapy Drugs)	N/A
510(k) Reference	K200960	K051378	N/A
Product Owner	Medline	Medline	Same
Product Code	LZA, LZC	LZA	Similar
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Similar

Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Design Configurations	Dark Blue	Blue	Similar
Materials	Nitrile	Nitrile	Same
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Limited ≤ 24 hours	Limited ≤ 24 hours	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Dimensions-Width	Complies with: ASTM D6319-10 70mm min	Complies with: ASTM D6319-10 70mm min	Same
Dimensions-Thickness	Complies with: ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Complies with: ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Same
Physical Properties	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Same
Freedom from holes	Complies with: ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Complies with: ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Residual Powder	Complies with ASTM D6319-10 <2mg per glove	Complies with ASTM D6319-10 <2mg per glove	Same
Biocompatibility	Complies with AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer AAMI/ANSI/ISO 10993-05 ISO 10993-11: Non-Toxic	Complies with AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	Similar

<table>
<tr>
<td>Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978</td>
<td>
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration</th><th>Breakthrough time</th></tr>
<tr><td>Carmustine (BCNU)</td><td>3.3 mg/ml (3,300 ppm)</td><td>12.4 minutes</td></tr>
<tr><td>Cisplatin</td><td>1.0 mg/ml (1,000 ppm)</td><td>>240 minutes</td></tr>
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</table>
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<tr><th>Chemotherapy Drug</th><th>Concentration</th><th>Breakthrough time</th></tr>
<tr><td>Cyclophosphamide</td><td>20.0 mg/ml (20,000 ppm)</td><td>No breakthrough up to 240 minutes</td></tr>
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<tr><td>Carmustine</td><td>3.3 mg/ml (3,300 ppm)</td><td>Not for use with Camustine</td></tr>
<tr><td>ThioTepa</td><td>10.0 mg/ml (10,000 ppm)</td><td>Not for use with Thiotepa</td></tr>
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<td>Similar</td>
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Summary of Non-Clinical Testing

The biocompatibility evaluation for the Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs) was conducted in accordance with ANSI/AAMI/ISO 10993- 1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA.

The following tests were performed to evaluate the biocompatibility of the Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-05: Cytotoxicity
- ISO 10993-11: Systemic Toxicity

Performance Testing (Bench)

Physical performance qualities of the proposed device were evaluated per ASTM D6319- 10, Standard Specification for Nitrile Examination Gloves for Medical Application. Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. In addition, the proposed device was tested according to ASTM D6978- 05 (Reapproved 2013), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

To summarize, the performance testing of the subject device were conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

ASTM D 6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D 6124-06 (Reaffirmation 2017) Standard Test Method for Residual Powder on Medical Gloves
ASTM D 5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves
ASTM D 6978-05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Conclusion

In accordance with 21 CFR part 807, and based on the non-clinical testing and information provided in this premarket notification Medline Industries, Inc. concludes that the Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed predicated device, Medline Powder Free Blue Nitrile Examination Glove (Tested for use with Chemotherapy Drugs) K051378.