September 18, 2020

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

Re: K201390
Trade/Device Name: Medline Powder-Free Light Blue Nitrile Exam 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, LZC
Dated: June 24, 2020
Received: June 25, 2020

Dear Adam 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); 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 CAPT Elizabeth Claverie, M.S.
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)*
K201390

Device Name
Medline Powder-Free Light Blue Nitrile Exam Gloves (Tested for Use with Chemotherapy)

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Carmustine (BCNU) 3.3 mg/ml 25.3 Minutes
Cisplatin 1.0 mg/ml ≥ 240 Minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml ≥ 240 Minutes
Dacarbazine (DTIC) 10.0 mg/ml ≥ 240 Minutes
Doxorubicin Hydrochloride 2.0 mg/ml ≥ 240 Minutes
Etoposide (Toposar) 20.0 mg/ml ≥ 240 Minutes
Fluorouracil 50.0 mg/ml 0.5 mg/ml ≥ 240 Minutes
Methotrexate 25 mg/ml ≥ 240 Minutes
Mitomycin C 0.5 mg/ml ≥ 240 Minutes
Paclitaxel (Taxol) 6.0 mg/ml ≥ 240 Minutes
Thio-Tepa 10.0 mg/ml 43.7 Minutes
Vincristine Sulfate (Oncovin) 1.0 mg/ml ≥ 240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 25.3 Minutes
Thio-Tepa 10.0 mg/ml 43.7 Minutes

Caution: Testing showed an average breakthrough time of 43.7 minutes with Thio-Tepa
WARNING: Do not use with Carmustine

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 (K201390)

[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: 224-931-1176
Email: aostrower@medline.com

Summary Preparation Date

September 18, 2020

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Medline Powder-Free Light Blue Nitrile Exam Glove (Tested for Use with Chemotherapy Drugs)
Common Name: Patient Examination Glove, Specialty
Classification Name: Patient Examination Glove, Specialty
Product Code: LZA, LZC
Classification Panel: General Hospital
Regulatory Class: I
Regulation Number: 21 CFR 880.6250

Predicate Device

Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs – K172525

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Device Description

The Medline Powder-Free Light Blue Nitrile Exam Gloves (Tested for Use with Chemotherapy Drugs) are single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, light blue colored, nitrile, and tested for use with chemotherapy drugs. The gloves are offered in four sizes: small, medium, large, and extra-large.

Indications for Use

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs, per ASTM D6978-05 *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

CHEMOTHERAPY DRUG TESTED		BREAKTHROUGH TIME (IN MINUTES)
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	25.3
Cisplatin	1.0 mg/ml (1,000 ppm)	≥ 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	≥ 240
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	≥ 240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	≥ 240
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	≥ 240
Fluorouracil	50.0 mg/ml (50,000 ppm)	≥ 240
Methotrexate	25 mg/ml (25,000 ppm)	≥ 240
Mitomycin C	0.5 mg/ml (500 ppm)	≥ 240
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	≥ 240
Thio-Tepa	10.0 mg/ml (10,000 ppm)	43.7
Vincristine Sulfate (Oncovin)	1.0 mg/ml (1,000 ppm)	≥ 240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 25.3 Minutes
Thio-Tepa 10.0 mg/ml 43.7 Minutes

CAUTION: Testing showed an average breakthrough time of 43.7 minutes with Thio-Tepa
WARNING: Do not use with Carmustine

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Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

DEVICE CHARACTERISTICS	PROPOSED DEVICE	PREDICATE DEVICE	COMPARISON ANALYSIS
Product Name	Powder-Free Light Blue Nitrile Exam Gloves (Tested for Use with Chemotherapy Drugs)	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Similar
510(k) Reference	K201390	K172525	
Product Owner	Medline Industries, Inc.	Central Medicare	Different
Product Code	LZA, LZC	LZA, LZC	Same
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 as per ASTM D6978-05(2019) *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Materials	Nitrile	Nitrile	Same
Color	Light Blue	Blue	Similar
Sizes	Small, Medium, Large, Extra Large	Extra-Small, Small, Medium, Large, Extra Large	Similar
Dimensions - Length	Complies with ASTM D6319-10 240mm min.	Complies with ASTM D6319-10 230mm min.	Different

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Dimensions - Width	Complies with ASTM D6319-10 XS: N/A S: 85±10 M: 95±10 L: 105±10 XL: 115±10	Complies with ASTM D6319-10 XS: 70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10	Similar
Dimensions - Thickness	Complies with ASTM D6319-10 Palm - 0.14 Finger - 0.16 Cuff - 0.12	Complies with ASTM D6319-10 Palm - 0.06±10 Finger - 0.08±10 Cuff - 0.10±10	Different
Physical Properties	Complies with ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥17 MPa, min After Aging ≥14 MPa, min	Tensile Strength: Before Aging ≥15 MPa, min After Aging ≥14 MPa, min	Similar
	Elongation: Before Aging 500% Min After Aging 400% Min	Elongation: Before Aging 500% Min After Aging 400% Min	Similar
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Freedom from Holes	Complies with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 2.5	In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-1	Same
Powder or Powder-Free	Powder-Free	Powder-Free	Same
Residual Powder	Max. 0.52mg per glove	Max. 0.52mg per glove	Same
Contact Duration	Limited 24 hours	Limited 24 hours	Same

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Biocompatibility	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer Cytotoxic Non-Toxic	Not a skin irritant Not a skin sensitizer	
Sterility	Non-Sterile	Non-Sterile	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978	Carmustine (BCNU) 3.3 mg/ml: 25.3 Minutes	Carmustine (3.3 mg/ml): 12.4 Minutes	Different
	Cisplatin 1.0 mg/ml: ≥240 Minutes	Cisplatin (1.0 mg/ml): ≥240 Minutes	Same
	Cyclophosphamide (Cytoxan) 20.0 mg/ml: ≥240 Minutes	Cyclophosphamide (20 mg/ml) : ≥240 Minutes	Same
	Dacarbazine (DTIC) 10.0 mg/ml: ≥240 Minutes	Dacarbazine (10.0 mg/ml): ≥240 Minutes	Same
	Doxorubicin Hydrochloride 2.0 mg/ml: ≥240 Minutes	Doxorubicin HCl (2.0 mg/ml): ≥240 Minutes	Same
	Etoposide (Toposar) 20.0 mg/ml: ≥240 Minutes	Etoposide (20.0 mg/ml): ≥240 Minutes	Same
	Fluorouracil 50.0 mg/ml: ≥240 Minutes	Fluorouracil (50.0 mh/ml): ≥240 Minutes	same
	Methotrexate 25 mg/ml: ≥240 Minutes	Not Tested	Different
	Mitomycin C 0.5 mg/ml: ≥ 240 Minutes	Not Tested	Different
	Not Tested	Mixotantrone (2.0 mg/ml): ≥240 Minutes	Different
	Paclitaxel (Taxol) 6.0 mg/ml: ≥240 Minutes	Paclitaxel (6.0 mg/ml): ≥240 Minutes	Same

	Thio-Tepa 10.0 mg/ml: 43.7 Minutes	Thiotepa (10.0 mg/ml): 24.4 Minutes	Different
	Vincristine Sulfate (Oncovin) 1.0 mg/ml: ≥240 Minutes	Vincristine Sulfate (1.0 mg/ml): ≥240 Minutes	Same

Summary of Non-Clinical Testing

The biocompatibility evaluation for Medline Powder-Free Light Blue Nitrile Exam Glove (Tested for Use with Chemotherapy Drugs) was conducted in accordance with ANSI/AAMI/ISO 10993-1:2009 *Biological Evaluation of Medical Devices – Part 1: Evaluation within a Risk Management Process*, as recognized by FDA.

The following tests were performed to evaluate the biocompatibility of the Medline Powder-Free Light Blue Nitrile Exam Glove (Tested for Use with Chemotherapy Drugs):

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

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 2019), 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.

In summary, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D 6124-06 (Reapproved 2011) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D 5151-06 (Reapproved 2011) Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D 6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Summary of Clinical Testing

No clinical study is included in this submission.

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Conclusion

In accordance with 21 CFR Part 807, and based on the nonclinical information provided in this premarket notification Medline Industries, Inc. concludes that Medline Powder-Free Light Blue Nitrile Exam Glove (Tested for Use with Chemotherapy Drugs) is as safe, as effective, and performs as well as or better for its intended use as the legally marketed predicate device, Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, K172525.