DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 19, 2016

Medline, Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, Illinois 60060

Re: K161473
Trade/Device Name: Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: September 14, 2016
Received: September 16, 2016

Dear Jennifer Mason:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K161473

Device Name
Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs)

Indications for Use *(Describe)*
A powder-free 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 were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemicals have been tested with these gloves.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

Carmustine 3.3mg/ml - 40.4 min.
Cisplatin 1.0mg/ml - No breakthrough up to 240 min.
Cyclophosphamide 20.0mg.ml - No breakthrough up to 240 min.
Dacarbazine 2.0mg/ml - No breakthrough up to 240 min.
Doxorubicin Hydrochloride 2/0mg.ml - No breakthrough up to 240 min.
Etoposide 20.0mg/ml - No breakthrough up to 240 min.
Fluoruouracil 50mg/ml - No breakthrough up to 240 min.
Methotrexate 25mg - No breakthrough up to 240 min.
Mitoxantrone 2.0mg/ml - No breakthrough up to 240 min.
Paclitaxel 5.0mg/ml - No breakthrough up to 240 min.
Thiotepa 10mg/ml - 60.6 min.

Please note that the following drugs have extremely low permeation times: Carmustine (3.3 mg/ml) has a minimum breakthrough time of 40.4 minutes; Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 60.6 minutes.

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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Medline Industries, Inc.
One Medline Place
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K161473
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060

Registration Number: 1417592

Contact Person
Jennifer Mason
Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: JAMason@medline.com

Summary Preparation Date
September 14, 2016

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs)
Proprietary Name: Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs)
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove
Product Code: LZA, LZC
Classification Panel: General Hospital
Regulatory Class: I
Regulation #: 21 CFR 880.6250

Predicate Device
EMG Blue Nitrile Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs K141623

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Device Description

The Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs) are single use only, disposable gloves intended for medical purposes to be worn on the hands or fingers of examiners. The gloves are powder-free and are made of nitrile with a blue colorant. The gloves are offered non-sterile and are available in small, medium, large and extra-large sizes.

Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. The subject device was tested according to ASTM D6978, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum breakthrough times were determined for a wide range of chemotherapy agents.

Indications for Use

A powder-free 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 were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The following chemicals have been tested with these gloves

Chemotherapy Drugs	Breakthrough Times
Carmustine 3.3mg/ml	40.4 min.
Cisplatin 1.0mg/ml	No breakthrough up to 240 min.
Cyclophosphamide 20.0mg/ml	No breakthrough up to 240 min.
Dacarbazine 2.0mg/ml	No breakthrough up to 240 min.
Doxorubicin Hydrochloride 2.0mg/ml	No breakthrough up to 240 min.
Etoposide 20.0mg/ml	No breakthrough up to 240 min.
Fluorouracil 50mg/ml	No breakthrough up to 240 min.
Methotrexate 25mg/ml	No breakthrough up to 240 min.
Mitoxantrone, 2.0mg/ml	No breakthrough up to 240 min.
Paclitaxel 5.0mg/ml	No breakthrough up to 240 min.
Thiotepa 10mg/ml	60.6 min.

Please note that the following drugs have extremely low permeation times: Carmustine (3.3 mg/ml) has a minimum breakthrough time of 40.4 minutes; Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 60.6 minutes.

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Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Powder-Free Blue Nitrile Exam Glove Extended Cuff (Tested for Use with Chemotherapy Drugs)	EMG Blue Nitrile Examination Gloves Powder Free with tested for use with chemotherapy drugs	Different
510(k) Reference	K161473	K141623	N/A
Product Owner	Medline Industries, Inc.	Eco Medi Glove SDN BHD	Different
Product Code	LZA, LZC	LZA, LZC	Same
Intended Use	A powder-free 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 and for use with chemotherapy drugs. In addition these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.	A powder-free 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 and for use with chemotherapy drugs. In additional these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by Chemotherapy drugs.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Materials	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Design Configurations	Small Medium Large Extra-Large	Small Medium Large Extra-Large	Same
Dimensions – Length	Complies with ASTM D6319-10 270mm min.	Complies with ASTM D6319-10 270mm min.	Same
Dimensions - Width	Complies with ASTM D6319-10 Small – 80 ±10mm min. Medium - 95±10mm min.	Complies with ASTM D6319-10 Small – 85 ±5mm min. Medium - 95±5mm min.	Same

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	Large - 110±10mm min. Extra-Large 120±10mm min.	Large - 105±5mm min. Extra-Large 115±5mm min.	
Dimensions - Thickness	Complies with ASTM D6319-10 Palm – 0.10mm min. Finger – 0.10mm min.	Complies with ASTM D6319-10 Palm – 0.10mm min. Finger – 0.10mm min.	Same
Physical Properties - Tensile	Complies with ASTM D6319-10 Before Aging - 14 MPa, min. After Aging - 14 MPa, min.	Complies with ASTM D6319-10 Before Aging – 14 MPa, min. After Aging – 14 MPa, min.	Same
Physical Properties - Elongation	Complies with ASTM D6319-10 Before Aging – 500% min. After Aging – 400% min.	Complies with ASTM D6319-10 Before Aging – 500% After Aging – 400%	Same
Freedom from Holes	AQL 1.5 Inspection level G-2 Meets ASTM D6319-10	AQL 2.5 Inspection level G-1 Meets ASTM D6319-00a	Similar
Residual Powder	Complies with ASTM D6319-10 < 2.0 mg	Complies with ASTM D6319-00a <2.0 mg	Same
Biocompatibility	ISO 10993-10:2010/(R) 2014 Under the conditions of the test, not an irritant	Under the conditions of the test, not an irritant	Same
	ISO 10993-10:2010/(R) 2014 Under the conditions of the test, not a skin sensitizer	Under the conditions of the test, not a skin sensitizer	
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use vs. Reusable	Single use	Single use	Same
Tested for Use with Chemotherapy Drugs	Yes ASTM 6978-05	Yes ASTM D6978-05	Same
Chemotherapy Drugs Tested	Carmustine 3.3mg/ml	Carmustine 3.3mg/ml	Similar
	Cisplatin 1.0mg/ml	-------	
	Cyclophosphamide 20.0mg/ml	Cyclophosphamide 20.0mg/ml	
	Dacarbazine 2.0mg/ml	--------	
	Doxorubicin Hydrochloride 2mg/ml	Doxorubicin Hydrochloride 2mg/ml	
	Etoposide 20.0mg.ml	Etoposide 20.0mg.ml	
	Fluorouracil 50 mg/ml	Fluorouracil 50 mg/ml	
	Methotrexate 25mg/ml	Methotrexate 25mg/ml	
	Mitoxantrone 2.0mg/ml	---------	
	Paclitaxel 5.0mg/ml	Paclitaxel 5.0mg/ml	
	Thiotepa 10mg/ml	Thiotepa 10mg/ml	
	---------	Cytarabine 100mg.ml	

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Summary of Non-Clinical Testing

The biocompatibility evaluation for the Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (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 and Testing Within a Risk Management Process, as recognized by FDA. The Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs) is classified as a surface contacting device with a limited contact duration of less than 24 hours.

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

- ISO 10993-10: Primary Skin Irritation Test
- ISO 10993-10: Closed Patch Sensitization Test

Performance Testing (Bench)

Physical performance qualities were evaluated per ASTM D6319, 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. The gloves were tested according to ASTM D6978, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum breakthrough times were determined for a wide range of chemotherapy drugs.

Summary of Clinical Testing

Not applicable.

Conclusion

Based on the non-clinical performance testing Medline Industries, Inc. concludes that the Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs) are as safe, as effective, and perform as well as the predicate device, EMG Blue Nitrile Medical Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs Labeling Claim (K141623). Therefore, the Medline Powder-Free Blue Nitrile Exam Glove, Extended Cuff (Tested for Use with Chemotherapy Drugs) are substantially equivalent to the predicate.