DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

February 27, 2017

Re: K162982
Trade/Device Name: Medline Nitrile Powder-free Examination Glove With Colloidal Oatmeal USP (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: January 31, 2017
Received: January 31, 2017

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,

Susan Runner DDS, MA

For Tina Kiang, Ph.D.
Acting Division 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)*
K162982

Device Name
Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (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.

These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Blenoxane (Bleomycin) 15 mg/ml >240 minutes
Bortezomib 1 mg/ml >240 minutes
Busulfan 6 mg/ml >240 minutes
Carboplatin 10.0 mg/ml >240 minutes
Carmustine (BCNU) 3.3 mg/ml 11.9 minutes
Cetuximab (Erbitux) 2 mg/ml >240 minutes
Cisplatin 1.0 mg.ml >240 minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes
Cytarabine 100 mg/ml >240 minutes
Dacarbazine (DTIC)10.0 mg/ml >240 minutes
Daunorubicin 5 mg/ml >240 minutes
Docetaxel 10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Ellence 2 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fludarabine 25 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Gemcitabine (Gemzar) 38 mg/ml >240 minutes
Idarubicin 1 mg/ml >240 minutes
Ifosfamide 50.0 mg/ml >240 minutes
Irinotecan 20.0 mg/ml >240 minutes
Mechlorethamine HCI 1.0 mg/ml >240 minutes
Melphalan 5 mg/ml >240 minutes
Methotrexate 25 mg/ml >240 minutes
Methotrexate 50 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Mitoxantrone 2.0 mg/ml >240 minutes
Oxaliplatin 5 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Paraplatin 10 mg/ml >240 minutes
Pemetrexed Disodium 25 mg/ml >240 minutes
Raltitrexed 0.5 mg/ml >240 minutes
Rituximab 10 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 18.6 minutes
Trisonex 0.1 mg/ml >240 minutes
Vidaza (5-Azacytidine) 25 mg/ml >240 minutes
Vinblastine 1 mg/ml >240 minutes

Vinorelbine 10 mg/ml >240 minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes

Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 11.9 minutes
Thiotepa (10.0 mg/ml) 18.6 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

K162982

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
February 27, 2017

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Patient Examination Glove (Tested for Use with Chemotherapy Drugs)
Proprietary Name: Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs)
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove
Product Code: LZA, LZC
Classification Panel: General Hospital
Regulation #: 21 CFR 880.6250

Predicate Device
Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Tested for Use with Chemotherapy Drugs
K160562

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

Reference Device

Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile. Tested for Use with Chemotherapy Drugs
K151750

Device Description

The Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) are non-sterile single use only, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between the patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, white colored nitrile gloves featuring an inner coating of colloidal oatmeal USP. The gloves are offered in five sizes, extra-small, small, medium, large and extra-large.

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

Indications for 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 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Tested	Breakthrough Time (in minutes)
Blenoxane 15 mg/ml	>240
Bortezomib 1 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine (BCNU) 3.3 mg/ml	11.9
Cetuximab (Eributux) 2 mg/ml	>240
Cisplatin 1.0 mg.ml	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC)10.0 mg/ml	>240
Daunorubicin 5 mg/ml	>240
Docetaxel 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Ellence 2 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fludarabine 25 mg/ml	>240

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

Fluorouracil 50.0 mg/ml	>240
Gemcitabine (Gemzar) 38 mg/ml	>240
Idarubicin 1 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Irinotecan 20.0 mg/ml	>240
Mechlorethamine HCI 1.0 mg/ml	>240
Melphalan 5 mg/ml	>240
Methotrexate 25 mg/ml	>240
Methotrexate 50 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Oxaliplatin 5 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Paraplatin 10 mg/ml	>240
Pemetrexed Disodium 25 mg/ml	>240
Raltitrexed 0.5 mg/ml	>240
Rituximab 10 mg/ml	>240
Thiotepa 10.0 mg/ml	18.6
Trisonex 0.1 mg/ml	>240
Vidaza (5-Azacytidine) 25 mg/ml	>240
Vinblastine 1 mg/ml	>240
Vinorelbine 10 mg/ml	>240
Vincristine Sulfate 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 11.9 minutes
Thiotepa (10.0 mg/ml) 18.6 minutes

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

Summary of Technological Characteristics

TABLE 1: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Reference Device	Comparison Analysis
Product Name	Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs)	Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Tested for Use with Chemotherapy Drugs	Powder Free Nitrile Patient Examination Glove, White Colored, Non Sterile. Tested for Use with Chemotherapy Drugs	N/A
510(k) Reference	K162982	K160562	K151750	N/A
Product Owner	Medline Industries, Inc.	Hartalega	Kossan	Different
Product Code	LZA, LZC	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 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	A non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs in accordance with ASTM D6978-05, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by 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. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Materials	Nitrile Colloidal oatmeal	Nitrile Colloidal oatmeal	Nitrile	Same as K160562
Color	White	White	White	Same

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

Sizes	x-small, small, medium, large, x-large	x-small, small, medium, large, x-large	x- small, small, medium, large, x-large, xx-large	Same
Dimensions – Length	Complies with ASTM D6319-10 230mm min.	Complies with ASTM D6319-10 240mm min.	Complies with ASTM D6319-10 230mm min.	Same as K151750 and similar to K160562 which is 10mm longer than the subject device.
Dimensions - Width	Complies with ASTM D6319-10 X-small – 70±10mm Small – 80±10mm Medium – 95±10mm Large – 110±10mm X-large – 120±10mm	Complies with ASTM D6319-10 Medium – 95mm	Complies with ASTM D6319-10 X-small – 70-80mm Small – 80-90mm Medium – 90-100mm Large – 101-11mm X-large – 111-121mm XX-large – 121-131mm	Same as K160562 and similar to K151750.
Dimensions - Thickness	Complies with ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Complies with ASTM D6319-10 Palm – 0.07mm min. Finger – 0.07mm min.	Complies with ASTM D6319-10 Palm – 0.05mm min. Finger – 0.05mm min.	Same as K151750 and similar to K160562
Physical Properties	Complies with ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min.	Complies with ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min.	Complies with ASTM D6319-10 minimum: Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min.	Same
	Elongation: Before Aging 500% min. After Aging 400% min.	Elongation: Before Aging 500%, min. After Aging 400%, min.	Elongation: Before Aging 500%, min. After Aging 400%, min.	
Freedom from Holes	Complies with ASTM D6319-10 and ASTM D5151-06 (reapproved 2011) G-1, AQL 1.5	Complies with ASTM D6319-10 and ASTM D5151-06 (reapproved 2011) AQL 1.5	Complies with ASTM D6319-10 and ASTM D5151-06 (reapproved 2011) G-1, AQL 1.5	Same
Powder or Powder-Free	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	Complies with ASTM D6319-10 <2mg per glove	Same

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

Contact Durations	Limited ≥24 hours	Limited ≥24 hours	Limited ≥24 hours	Same
Biocompatibility	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	Same
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978	Blenoxane 15 mg/ml >240 min.			Different
	Bortezomib 1 mg/ml >240 min.			Different
	Busulfan 6 mg/ml >240 min.			Different
	Carmustine (BCNU) 3.3 mg/ml 11.9 min.	Carmustine 3.3 mg/ml 10.1 min.	Carmustine (BCNU) 3.3 mg/ml 10.1 min.	Same
	Cetuximab (Erbitux) 2 mg/ml >240 min.			Different
	Cisplatin 1.0 mg.ml >240 min.	Cisplatin 1.0 mg.ml >240 min.	Cisplatin 1.0 mg.ml >240 min.	Same
	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	Cyclophosphamide (Cytoxan) 20 mg/ml >240 min.	Cyclophosphamide (Cytoxan) 20 mg/ml >240 min.	Same
	Cytarabine 100 mg/ml >240 min.		Cytarabine 100 mg/ml >240 min.	Different
	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Same
	Daunorubicin 5 mg/ml >240 min.			Different
	Docetaxel 10.0 mg/ml >240 min.			Different
	Doxorubicin Hydrochloride 2.0 mg/ml >240 min.	Doxorubicin Hydrochloride 2.0 mg/ml >240 min.	Doxorubicin Hydrochloride 2.0 mg/ml >240 min.	Same
	Ellence 2 mg/ml >240 min.			Different
	Etoposide (Toposar) 20.0 mg/ml >240 min.	Etoposide (Toposar) 20.0 mg/ml >240 min.	Etoposide (Toposar) 20.0 mg/ml >240 min.	Same
	Fludarabine 25 mg/ml >240 min.			Different

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

	Fluorouracil 50.0 mg/ml >240 min.	Fluorouracil 50.0 mg/ml >240 min.	Fluorouracil 50.0 mg/ml >240 min.	Same
	Gemcitabine (Gemzar) 38 mg/ml >240 min.			Different
	Idarubicin 1 mg/ml >240 min.			Different
	Ifosfamide 50.0 mg/ml >240 min.		Ifosfamide (IFEX) 50 mg/ml >240 min.	Different
	Irinotecan 20.0 mg/ml >240 min.			Different
	Mechlorethamine HCI 1.0 mg/ml >240 min.			Different
	Melphalan 5 mg/ml >240 min.			Different
	Methotrexate 25 mg/ml >240 min.	Methotrexate 25 mg/ml >240 min	Methotrexate 25 mg/ml >240 min.	Same
	Methotrexate 50 mg/ml >240 min.			Different
	Mitomycin C 0.5 mg/ml >240 min.	Mitomycin C 0.5 mg/ml >240 min.	Mitomycin C 0.5 mg/ml >240 min.	Same
	Mitoxantrone 2.0 mg/ml >240 min.		Mitoxantrone 2.0 mg/ml >240 min.	Different
	Oxaliplatin 5 mg/ml >240 min.			Different
	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Same
	Paraplatin 10 mg/ml >240 min.			Different
	Pemetrexed Disodium 25 mg/ml >240 min.			Different
	Raltitrexed 0.5 mg/ml >240 min.			Different
	Rituximab 10 mg/ml >240 min.			Different
	Thiotepa 10.0 mg/ml 18.6 min.	Thiotepa 10.0 mg/ml 30.4 min.	Thiotepa 10.0 mg/ml 10.4 min.	Same
	Trisonex 0.1 mg/ml >240 min.			Different

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

	Vidaza (5-Azacytidine) 25 mg/ml >240 min.			Different
	Vinblastine 1 mg/ml >240 min.			Different
	Vinorelbine 10 mg/ml >240 min.			Different
	Vincristine Sulfate 1.0 mg/ml >240 min.	Vincristine Sulfate 1.0 mg/ml >240 min.	Vincristine Sulfate (Oncovin) 1.0 mg/ml >240 min.	Same

Summary of Non-Clinical Testing

The biocompatibility evaluation for the Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (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 following tests were performed to evaluate the biocompatibility of the Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs):

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D 6124-06 (Reaffirmation 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 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Performance Testing (Bench)

Physical performance qualities 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. The gloves were tested according to ASTM D6978- 05 (Reapproved 2013), Standard

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

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

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) is as safe and as effective for their intended use as the predicate device, the Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Tested for Use with Chemotherapy Drugs, K160562.

.