April 30, 2018

Medline Industries, Inc.
Pauline Maralit
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, IL 60093

Re: K180696
Trade/Device Name: Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal (Tested for use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: March 8, 2018
Received: March 16, 2018

Dear Pauline Maralit:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180696

Device Name
Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves 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.
Carmustine (BCNU) 3.3 mg/ml 13.2 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 >240 minutes
Methotrexate 25.0 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 44.0 minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes

Please note that the following drug has extremely low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 13.2 minutes

Please note that the following drug has low permeation times:
Thiotepa (10.0 mg/ml) 44.0 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.**
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# K180696

## Submitter / 510(k) Sponsor

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

## Contact Person

Pauline Maralit
Regulatory Affairs Specialist
Phone: 847-949-2283
Email: pmaralit@medline.com

## Summary Preparation Date

April 18, 2018

## Type of 510(k) Submission

Traditional

## Device Name / Classification

Name of Device: Patient Examination Glove (Tested for Use with Chemotherapy Drugs)
Proprietary Name: Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves 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

Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) - K162982

**Medline Industries, Inc.**
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## Device Description

The Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for use with Chemotherapy Drugs) are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are powder-free, ambidextrous with beaded cuff, green 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 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

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.

**TABLE 1: Chemotherapy Drugs Tested**

| Chemotherapy Drug Tested | Breakthrough Time (in minutes) |
|---|---|
| Carmustine (BCNU) 3.3 mg/ml | 13.2 |
| Cisplatin 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) 20.0 mg/ml | >240 |
| Dacarbazine (DTIC)10.0 mg/ml | >240 |
| Doxorubicin Hydrochloride 2.0 mg/ml | >240 |
| Etoposide (Toposar) 20.0 mg/ml | >240 |
| Fluorouracil 50.0 mg/ml | >240 |
| Methotrexate 25.0 mg/ml | >240 |
| Mitomycin C 0.5 mg/ml | >240 |
| Paclitaxel (Taxol) 6.0 mg/ml | >240 |
| Thiotepa 10.0 mg/ml | 44.0 |
| Vincristine Sulfate 1.0 mg/ml | >240 |

Please note that the following drug has extremely low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 13.2 minutes.
Please note that the following drug has low permeation times:
Thiotepa (10.0 mg/ml) 44.0 minutes.

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## Summary of Technological Characteristics

**TABLE 2: Comparison of Proposed and Predicate Devices**

| Device Characteristic | Proposed Device | Predicate Device | Comparison Analysis |
|---|---|---|---|
| **Product Name** | Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for use with Chemotherapy Drugs) | Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) | **N/A** |
| **510(k) Reference** | K180696 | K162982 | **N/A** |
| **Product Owner** | Medline Industries, Inc. | Medline Industries, Inc. | **Same** |
| **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.<br><br>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 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.<br><br>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 | **Same** |
| **Materials** | Nitrile, Colloidal Oatmeal | Nitrile, Colloidal Oatmeal | **Same** |
| **Oatmeal Content** | Min. 5mg for all sizes | Min. 5mg for all sizes | **Same** |
| **Color** | Green | White | **Similar** |
| **Sizes** | x- small, small, medium, large, x-large | x-small, small, medium, large, x-large | **Same** |
| **Dimensions –** | Complies with ASTM D6319- | Complies with ASTM D6319- | **Same** |

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| | | | |
|---|---|---|---|
| **Length** | 10<br>220mm min. | 10<br>230mm min. | |
| **Dimensions - Width** | Complies with ASTM D6319-10<br>X-small – 70±10mm<br>Small – 80±10mm<br>Medium – 95±10mm<br>Large – 110±10mm<br>X-large – 120±10mm | Complies with ASTM D6319-10<br>X-small – 70±10mm<br>Small – 80±10mm<br>Medium – 95±10mm<br>Large – 110±10mm<br>X-large – 120±10mm | **Same** |
| **Dimensions - Thickness** | Complies with ASTM D6319-10<br>Palm – 0.05mm min.<br>Finger – 0.05mm min. | Complies with ASTM D6319-10<br>Palm – 0.05mm min.<br>Finger – 0.05mm min. | **Same** |
| **Physical Properties** | Complies with ASTM D6319-10 minimum:<br><br>Tensile Strength:<br>Before Aging ≥14 MPa, min.<br>After Aging ≥14 MPa, min. | Complies with ASTM D6319-10 minimum:<br><br>Tensile Strength:<br>Before Aging ≥14 MPa, min.<br>After Aging ≥14 MPa, min. | **Same** |
| | Elongation:<br>Before Aging 500%, min.<br>After Aging 400%, min. | Elongation:<br>Before Aging 500% min.<br>After Aging 400% min. | |
| **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** |
| **Contact Durations** | Limited ≤24 hours | Limited ≤24 hours | **Same** |
| **Biocompatibility** | AAMI/ANSI/ISO 10993-10:<br>Not a skin irritant<br>Not a skin sensitizer | AAMI/ANSI/ISO 10993-10:<br>Not a skin irritant<br>Not a skin sensitizer | **Same** |
| **Sterility** | Non-sterile | Non-sterile | **Same** |
| **Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978** | | Blenoxane 15 mg/ml<br>>240 min. | **Different** |
| | | Bortezomib 1 mg/ml<br>>240 min. | **Different** |
| | | Busulfan 6 mg/ml<br>>240 min. | **Different** |
| | Carmustine (BCNU) 3.3 mg/m | Carmustine (BCNU) 3.3 mg/ml | **Similar** |

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| | | | |
|---|---|---|---|
| | 13.2 min. | 11.9 min. | |
| | | Cetuximab (Erbitux) 2 mg/ml >240 min. | **Different** |
| | Cisplatin 1.0 mg/ml >240 min. | Cisplatin 1.0 mg.ml >240 min. | **Same** |
| | Cyclophosphamide (Cytoxan) 20 mg/ml >240 min. | Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min. | **Same** |
| | | Cytarabine 100 mg/ml >240 min. | **Different** |
| | 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. | **Same** |
| | | Ellence 2 mg/ml >240 min. | **Different** |
| | Etoposide (Toposar) 20.0 mg/ml >240 min. | Etoposide (Toposar) 20.0 mg/ml >240 min. | **Same** |
| | | Fludarabine 25 mg/ml >240 min. | **Different** |
| | 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. | **Different** |
| | | Irinotecan 20.0 mg/ml >240 min. | **Different** |
| | | Mechlorethamine HCl 1.0 mg/ml | **Different** |

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| | | | |
|---|---|---|---|
| | | >240 min. | |
| | | Melphalan 5 mg/ml<br>>240 min. | **Different** |
| | Methotrexate 25 mg/ml<br>>240 min. | Methotrexate 25 mg/ml<br>>240 min. | **Same** |
| | | Methotrexate 50 mg/ml<br>>240 min. | **Different** |
| | Mitomycin C 0.5 mg/ml<br>>240 min. | Mitomycin C 0.5 mg/ml<br>>240 min. | **Same** |
| | | Mitoxantrone 2.0 mg/ml<br>>240 min. | **Different** |
| | | Oxaliplatin 5 mg/ml<br>>240 min. | **Different** |
| | Paclitaxel (Taxol) 6.0 mg/ml<br>>240 min. | Paclitaxel (Taxol) 6.0 mg/ml<br>>240 min. | **Same** |
| | | Paraplatin 10 mg/ml<br>>240 min. | **Different** |
| | | Pemetrexed Disodium 25 mg/ml<br>>240 min. | **Different** |
| | | Raltitrexed 0.5 mg/ml<br>>240 min. | **Different** |
| | | Rituximab 10 mg/ml<br>>240 min. | **Different** |
| | Thiotepa 10.0 mg/ml<br>44.0 min. | Thiotepa 10.0 mg/ml<br>18.6 min. | **Similar** |
| | | Trisonex 0.1 mg/ml<br>>240 min. | **Different** |
| | | Vidaza (5-Azacytidine) 25 mg/ml<br>>240 min. | **Different** |
| | | Vinblastine 1 mg/ml<br>>240 min. | **Different** |
| | | Vinorelbine 10 mg/ml<br>>240 min. | **Different** |
| | Vincristine Sulfate 1.0 mg/ml<br>>240 min. | Vincristine Sulfate 1.0 mg/ml<br>>240 min. | **Same** |

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## Summary of Non-Clinical Testing

The biocompatibility evaluation for Medline Green Ambidextrous Powder-Free Nitrile 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 Medline Green Ambidextrous Powder-Free Nitrile Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs):

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

In lieu of cytotoxicity and acute systemic toxicity testing for the Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for use with Chemotherapy Drugs), a Certificate of Analysis was provided for the color imparting compound to demonstrate it met its technical specifications and was safe for the intended use.

## 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.

- 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

## Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that Medline Green Ambidextrous Powder-Free Nitrile Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) is as safe and effective for its intended use as the predicate device, the Medline Nitrile Powder-Free Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs), cleared under K162982.