January 10, 2020

Medline Industries, Inc.
Claire Pigman
Associate Manager, Regulatory Affairs
Three Lakes Drive
Northfield, Illinois 60093

Re: K192315
Trade/Device Name: Medline Green Ambidextrous Power-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: December 6, 2019
Received: December 10, 2019

Dear Claire Pigman:

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 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192315

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.
Blenoxane (Bleomycin) 15.0 mg/ml >240 minutes
Bortezomib 1.0 mg/ml >240 minutes
Busulfan 6.0 mg/ml >240 minutes
Carboplatin 10.0 mg./ml >240 minutes
Carmustine (BCNU) 3.3 mg/ml 13.2 minutes
Cetuximab (Eributux) 2.0 mg/ml >240 minutes
Cisplatin 1.0 mg/ml >240 minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes
Dacarbazine (DTIC)10.0 mg/ml >240 minutes
Docetaxel 10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Epirubicin (Ellence) 2.0 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fludarabine 25.0 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Gemcitabine (Gemzar) 38.0 mg/ml >240 minutes
Idarubicin 1.0 mg/ml >240 minutes
Ifosfamide 50.0 mg/ml >240 minutes
Irinotecan 50.0 mg/ml >240 minutes
Mechlorethamine HCI 1.0 mg/ml >240 minutes
Melphalan 5.0 mg/ml >240 minutes
Methotrexate 25.0 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Mitoxantrone 2.0 mg/ml >240 minutes
Oxaliplatin 5.0 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Paraplatin 10.0 mg/ml >240 minutes
Pemetrexed 25.0 mg/ml >240 minutes
Raltitrexed 0.5 mg/ml >240 minutes
Rituximab 10.0 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 44 minutes
Trisonex (Arsenic Trioxide) 1.0 mg/ml >240 minutes
Vidaza (Azacitidine) 25.0 mg/ml >240 minutes
Vinblastine 1.0 mg/ml >240 minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes
Vinorelbine 10.0 mg/ml >240 minutes

Please note that the following drug has extremely low permeation time:
Carmustine (BCNU) (3.3 mg/ml) 13.2 minutes
Please note that the following drug has extremely low permeation time:
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.
Three Lakes Drive
Northfield, IL 60093

K192315

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

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Claire Pigman
Associate Manager, Regulatory Affairs
Phone: 847-643-4071
Email: cpigman@medline.com

Summary Preparation Date
January 9, 2020

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 Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs) – K180696

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

Device Description

There have been no changes to the Medline Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs). The materials of construction, colorant, sizes and product specifications have not changed and are identical to what was cleared under K180696. The only change is to the Indications for Use.

As previously described in K180696, 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 per ASTM D6978-05 (Reapproved 2013) *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*.
Blenoxane (Bleomycin) 15.0 mg/ml >240 minutes
Bortezomib 1.0 mg/ml >240 minutes
Busulfan 6.0 mg/ml >240 minutes
Carboplatin 10.0 mg./ml >240 minutes
Carmustine (BCNU) 3.3 mg/ml 13.2 minutes
Cetuximab (Eributux) 2.0 mg/ml >240 minutes
Cisplatin 1.0 mg/ml >240 minutes
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes
Dacarbazine (DTIC)10.0 mg/ml >240 minutes
Docetaxel 10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Epirubicin (Ellence) 2.0 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fludarabine 25.0 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Gemcitabine (Gemzar) 38.0 mg/ml >240 minutes
Idarubicin 1.0 mg/ml >240 minutes
Ifosfamide 50.0 mg/ml >240 minutes
Irinotecan 50.0 mg/ml >240 minutes

Mechlorethamine HCI 1.0 mg/ml >240 minutes
Melphalan 5.0 mg/ml >240 minutes
Methotrexate 25.0 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Mitoxantrone 2.0 mg/ml >240 minutes
Oxaliplatin 5.0 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Paraplatin 10.0 mg/ml >240 minutes
Pemetrexed 25.0 mg/ml >240 minutes
Raltitrexed 0.5 mg/ml >240 minutes
Rituximab 10.0 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 44 minutes
Trisonex (Arsenic Trioxide) 1.0 mg/ml >240 minutes
Vidaza (Azacitidine) 25.0 mg/ml >240 minutes
Vinblastine 1.0 mg/ml >240 minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes
Vinorelbine 10.0 mg/ml >240 minutes

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

Summary of Technological Characteristics

Table 1 Comparison of Proposed and Predicate Device

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 Green Ambidextrous Powder-Free Nitrile Examination Gloves with Colloidal Oatmeal USP (Tested for use with Chemotherapy Drugs)	**Same**
510(k) Reference	K192315	K180696	**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	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent	**Same**

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	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	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	
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	**Same**
Materials	Nitrile Colloidal oatmeal	Nitrile Colloidal oatmeal	**Same**
Color	Green	Green	**Same**
Sizes	x- small, small, medium, large, x-large	x-small, small, medium, large, x-large	**Same**
Dimensions – Length	Complies with ASTM D6319-10 220mm min.	Complies with ASTM D6319-10 230mm min.	**Same**
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 X-small – 70±10mm Small – 80±10mm Medium – 95±10mm Large – 110±10mm X-large – 120±10mm	**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.	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.	
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**

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Colloidal Oatmeal Content	Minimum 5mg per glove for all sizes	Minimum 5mg per glove for all sizes	**Same**
Contact Durations	Limited ≤24 hours	Limited ≤24 hours	**Same**
Biocompatibility per ISO 10993-1	Not a skin irritant Not a skin sensitizer At the neat extraction, the test article is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect.	Not a skin irritant Not a skin sensitizer Not tested against cytotoxicity	**Same**
Sterility	Non-sterile	Non-sterile	**Same**
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978	Blenoxane (Bleomycin) 15 mg/ml >240 min.		**Similar**
	Bortezomib 1 mg/ml >240 min.		**Similar**
	Busulfan 6 mg/ml >240 min.		**Similar**
	Carboplatin 10 mg/ml >240 min.		**Similar**
	Carmustine (BCNU) 3.3 mg/ml 13.2 min.	Carmustine (BCNU) 3.3 mg/ml 13.2 min.	**Same**
	Cetuximab (Erbitux) 2 mg/ml >240 min.		**Similar**
	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**
	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Dacarbazine (DTIC)10.0 mg/ml >240 min.	**Same**
	Docetaxel 10.0 mg/ml >240 min.		**Similar**
	Doxorubicin Hydrochloride 2.0 mg/ml >240 min.	Doxorubicin Hydrochloride 2.0 mg/ml >240 min.	**Same**
	Epirubicin (Ellence) 2.0 mg/ml >240 min.		**Similar**
	Etoposide (Toposar) 20.0 mg/ml >240 min.	Etoposide (Toposar) 20.0 mg/ml >240 min.	**Same**
	Fludarabine 25 mg/ml >240 min.		**Similar**
	Fluorouracil 50.0 mg/ml >240 min.	Fluorouracil 50.0 mg/ml >240 min.	**Same**

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	Gemcitabine (Gemzar) 38 mg/ml >240 min.		**Similar**
	Idarubicin 1 mg/ml >240 min.		**Similar**
	Ifosfamide 50.0 mg/ml >240 min.		**Similar**
	Irinotecan 20.0 mg/ml >240 min.		**Similar**
	Mechlorethamine HCI 1.0 mg/ml >240 min.		**Similar**
	Melphalan 5 mg/ml >240 min.		**Similar**
	Methotrexate 25 mg/ml >240 min.	Methotrexate 25 mg/ml >240 min.	**Same**
	Mitromycin C. 0.5 mg/ml >240	Mitromycin C. 0.5 mg/ml >240	**Same**
	Mitoxantrone 2.0 mg/ml >240 min.		**Similar**
	Oxaliplatin 5 mg/ml >240 min.		**Similar**
	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	**Same**
	Paraplatin 10 mg/ml >240 min.		**Similar**
	Pemetrexed Disodium 25 mg/ml >240 min.		**Similar**
	Raltitrexed 0.5 mg/ml >240 min.		**Similar**
	Rituximab 10 mg/ml >240 min.		**Similar**
	Thiotepa 10.0 mg/ml 44.0 min.	Thiotepa 10.0 mg/ml 44.0 min.	**Same**
	Trisonex 0.1 mg/ml >240 min.		**Similar**
	Vidaza (5-Azacytidine) 25 mg/ml >240 min		**Similar**
	Vinblastine 1 mg/ml >240 min.		**Similar**
	Vinorelbine 10 mg/ml >240 min.		**Similar**
	Vincristine Sulfate 1.0 mg/ml >240 min.	Vincristine Sulfate 1.0 mg/ml >240 min.	**Same**

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Summary of Non-Clinical Testing

Biocompatibility

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 10993-1:2018 *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 Medline Green Ambidextrous Powder-Free Nitrile Examination Glove with Colloidal Oatmeal USP (Tested for Use with Chemotherapy Drugs):

Table 2 Biocompatibility Testing Summary

Test Standard	Test Standard Description	Acceptance Criteria	Result
ISO 10993-10	Primary Skin Irritation	Cutaneous macroscopical examinations are performed after removal of test material. The appearance of each application site and skin reaction observed are scored.	No skin reactions observed. Not a skin irritant.
ISO 10993-10	Dermal Sensitization	Challenge sites are visually assessed for allergic reactions and the intensity of the reaction is scored.	No positive allergic reactions observed. Not a skin sensitizer
ISO 10993-5	Cytotoxicity	Test articles scoring '0', '1', or '2' are considered 'non-cytotoxic.' Test articles scoring '3' or '4' are considered 'cytotoxic.'	At the neat extraction, the test article is considered cytotoxic.
ISO 10993-11	Acute Systemic Toxicity	Abnormal clinical signs indicative of toxicity during the 72 hours test period are observed and reported.	No signs of toxicity at any of the observation periods were observed.

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. Additionally, 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 following tests were performed to evaluate the functional performance of the subject device:

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Northfield, IL 60093

Table 3 Performance Testing Summary

Test Standard	Test Standard Description	Acceptance Criteria	Result
ASTM D6319-10	Standard Specification for Nitrile Examination Gloves for Medical Application	Samples shall meet specified physical dimensions in accordance with the standard.	All device dimensions meet the standard.
ASTM D6124-06 (Reaffirmation 2011)	Standard Test Method for Residual Powder on Medical Gloves	< 2mg of residual powder per glove.	Complies with standard.
ASTM D5151-06 (Reapproved 2011)	Standard Test Method for Detection of Holes in Medical Gloves	Any glove that shows a droplet, stream or other type of water leakage shall be considered to have failed.	Complies with standard.
ASTM D6978-05 (Reapproved 2013)	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	The absorbance of test chemicals, which permeate through the test articles, is measured and reported.	Refer to Table 1 above.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K180696).