August 4, 2020

Leontyne Banks
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K193666
Trade/Device Name: Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy and Fentanyl) - Regular Cuff; Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, OPJ
Dated: June 10, 2020
Received: June 10, 2020

Dear Leontyne Banks:

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,

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

Indications for Use

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

510(k) Number *(if known)*

K193666

Device Name

Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff

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.

Chemo Drugs Tested:	Breakthrough Time (Minutes)
Aresenic Trioxide 1 mg/ml (1,000 ppm)	>240
Azacitidine 25 mg/ml (25,000 ppm)	>240
Bendamustine 5 mg/ml (5,000 ppm)	>240
Bleomycin 15 mg/ml (15,000 ppm)	>240
Bortezomib 1 mg/ml (1,000 ppm)	>240
Busulfan 6 mg/ml (6,000 ppm)	>240
Carboplatin 10.0 mg/ml (10,000 ppm)	>240
Carfilzomib 2.0 mg/ml (2,000)	>240
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	33.1 min
Cetuximab 2.0 mg/ml (2,000)	>240
Cisplatin 1.0 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	>240
Cytarabine 100 mg/ml (100,000 ppm)	>240
Cytovene 10 mg/ml (10,000 ppm)	>240
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	>240
Daunorubicin 5 mg/ml (5,000 ppm)	>240
Decitabine 5 mg/ml (5,000 ppm)	>240
Docetaxel 10.0 mg/ml (10,000 ppm)	>240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	>240
Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm)	>240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	>240
Fludarabine 25 mg/ml (25,000 ppm)	>240
Fluorouracil 50.0 mg/ml (50,000 ppm)	>240
Fulvestrant 50.0 mg/ml (50,000 ppm)	>240
Gemcitabine (Gemzar) 38 mg/ml (38,000 ppm)	>240
Idarubicin 1 mg/ml (1,000 ppm)	>240
Ifosfamide 50.0 mg/ml (50,000 ppm)	>240
Irinotecan 20.0 mg/ml (20,000 ppm)	>240
Mechlorethamine HCI 1.0 mg/ml (1,000 ppm)	>240
Melphalan 5 mg/ml (5,000 ppm)	>240
Methotrexate 25 mg/ml (25,000 ppm)	>240
Mitomycin C 0.5 mg/ml (500 ppm)	>240
Mitoxantrone 2.0 mg/ml (2,000 ppm)	>240
Oxaliplatin 2.0 mg/ml (2,000 ppm)	>240
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	>240
Paraplatin 10 mg/ml (10,000 ppm)	>240
Pemetrexed Disodium 25.0 mg/ml (25,000 ppm)	>240
Pertuzumab 30 mg/ml (30,000 ppm)	>240
Raltitrexed 0.5 mg/ml (500 ppm)	>240

Retrovir 10.0 mg/ml (10,000 ppm)	>240
Rituximab 10 mg/ml (10,000 ppm)	>240
Temsirolimus 25.0 mg/ml (25,000 ppm)	>240
Thiotepa 10.0 mg/ml (10,000 ppm)	69.2 min
Topotecan HCI 1.0 mg/ml (1,000 ppm)	>240
Trastuzumab 21.0 mg/ml (21,000 ppm)	>240
Trisonex 1 mg/ml (1,000 ppm)	>240
Vinblastine 1 mg/ml (1,000 ppm)	>240
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240
Vinorelbine 10 mg/ml (10,000 ppm)	>240
Zoledronic Acid 0.8 mg/ml (800 ppm)	>240
Fentanyl Citrate, 100mcg/2mL	>240

Please note that the following drug has low permeation time:
Carmustine (BCNU) (3.3 mg/ml) 33.1 minutes
Thiotepa (THT) (10.0mg/ml) 69.2 minutes
CAUTION: Testing showed an average breakthrough time of 33.1 minutes with Carmustine and 69.2 minutes with Thiotepa

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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Indications for Use

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

510(k) Number *(if known)*

K193666

Device Name

Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff

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.

Chemotherapy Drug Tested	Breakthrough Time (in minutes)
Aresenic Trioxide 1 mg/ml	>240
Azacitidine 25 mg/ml	>240
Bendamustine 5 mg/ml	>240
Bleomycin 15 mg/m	>240
Bortezomib 1 mg/ml	>240
Busulfan 6 mg/ml	>240
Carfilzomib 2 mg/ml	>240
Carmustine (BCNU) 3.3 mg/ml	59.4 min
Cetuximab	>240
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240
Cytarabine Hydrochloride 100 mg/ml	>240
Cytovene 10 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240
Daunorubicin 5 mg/ml	>240
Decitabine 5 mg/ml	>240
Docetaxel 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Epirubicin (Ellence) 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fludarabine 25 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Fulvestrant 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 25.0 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2mg/ml	>240
Oxaliplatin 5.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Paraplatin (Carboplatin) 10 mg/ml	>240
Pemetrexed Disodium 25.0 mg/ml	>240
Pertuzumab 30 mg/ml	>240
Raltitrexed 0.5 mg/ml	>240
Retrovir 10.0 mg/ml	>240

Rituximab 10 mg/ml	>240
Temsirolimus 25.0 mg/ml	>240
Thiotepa 10.0 mg/ml	68.2 min
Topotecan HCI 1.0 mg/ml	>240
Trastuzumab 21.0 mg/ml	>240
Trisonex 1 mg/ml	>240
Vinblastine 1 mg/ml	>240
Vincristine Sulfate 1.0 mg/ml	>240
Vinorelbine 10 mg/ml	>240
Zoledronic Acid 0.8 mg/ml	>240
Fentanyl Citrate, 100mcg/2mL	>240

Please note that the following drug has low permeation time:
Carmustine (BCNU) (3.3 mg/ml) 59.4 minutes
Thiotepa (THT) (10.0 mg/ml) 68.2 minutes
CAUTION: Testing showed an average breakthrough time of 59.4 minutes with Carmustine and 68.2 minutes with Thiotepa

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)

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

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

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592
Applicant Contact: Leontyne Banks
Regulatory Affairs Specialist

Summary Preparation Date
July 31, 2020

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff; Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff
Proprietary Name: Medline Powder-Free Blue Nitrile Patient Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff; Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff
Common Name: Patient Examination Glove, Specialty
Classification Name: Polymer Patient Exam Glove, Medical Gloves with Chemotherapy/Fentanyl Labeling Claims
Product Code: LZA, OPJ, QDO
Classification Panel: General Hospital
Regulation #: 21 CFR 880.6250

Predicate Device
YTY Industry (Manjung): Non-Sterile, Powder-Free Nitrile Examination Gloves (Cobalt Blue) Tested for use with Chemotherapy Drugs – K111248

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

Device Description

The Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff 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 nitrile, powder-free, ambidextrous, and blue-colored with a beaded cuff. The proposed device is offered in two versions: Regular cuff (VS311) and Extended cuff (VS711).

TABLE 1: The Medline Powder-Free Blue Nitrile Examination Gloves – Regular Cuff Sizes

Model Number	Size
VS311XS	Extra-Small
VS311S	Small
VS311M	Medium
VS311L	Large
VS311XL	Extra-Large

TABLE 2: The Medline Powder-Free Blue Nitrile Examination Gloves – Extended Cuff Sizes

Model Number	Size
VS711XS	Extra-Small
VS711S	Small
VS711M	Medium
VS711L	Large
VS711XL	Extra-Large

The gloves are designed and manufactured in accordance with the ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application and are tested for use with chemotherapy drugs as well as for use with Fentanyl per ASTM D6978-05 (Reapproved 2019).

Indications for Use – Regular Cuff (VS311XS, VS311S, VS311M, VS311L and VS311XL)

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

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for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs

Chemo Drugs Tested:	Breakthrough Time (Minutes)
Aresenic Trioxide 1 mg/ml (1,000 ppm)	>240
Azacitidine 25 mg/ml (25,000 ppm)	>240
Bendamustine 5 mg/ml (5,000 ppm)	>240
Bleomycin 15 mg/ml (15,000 ppm)	>240
Bortezomib 1 mg/ml (1,000 ppm)	>240
Busulfan 6 mg/ml (6,000 ppm)	>240
Carboplatin 10.0 mg/ml (10,000 ppm)	>240
Carfilzomib 2.0 mg/ml (2,000)	>240
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	33.1 min
Cetuximab 2.0 mg/ml (2,000)	>240
Cisplatin 1.0 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	>240
Cytarabine 100 mg/ml (100,000 ppm)	>240
Cytovene 10 mg/ml (10,000 ppm)	>240
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	>240
Daunorubicin 5 mg/ml (5,000 ppm)	>240
Decitabine 5 mg/ml (5,000 ppm)	>240
Docetaxel 10.0 mg/ml (10,000 ppm)	>240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	>240
Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm)	>240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	>240
Fludarabine 25 mg/ml (25,000 ppm)	>240
Fluorouracil 50.0 mg/ml (50,000 ppm)	>240
Fulvestrant 50.0 mg/ml (50,000 ppm)	>240
Gemcitabine (Gemzar) 38 mg/ml (38,000 ppm)	>240
Idarubicin 1 mg/ml (1,000 ppm)	>240
Ifosfamide 50.0 mg/ml (50,000 ppm)	>240
Irinotecan 20.0 mg/ml (20,000 ppm)	>240
Mechlorethamine HCl 1.0 mg/ml (1,000 ppm)	>240
Melphalan 5 mg/ml (5,000 ppm)	>240
Methotrexate 25 mg/ml (25,000 ppm)	>240
Mitomycin C 0.5 mg/ml (500 ppm)	>240
Mitoxantrone 2.0 mg/ml (2,000 ppm)	>240
Oxaliplatin 2.0 mg/ml (2,000 ppm)	>240
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	>240

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Northfield, IL 60093

Paraplatin 10 mg/ml (10,000 ppm)	>240
Pemetrexed Disodium 25.0 mg/ml (25,000 ppm)	>240
Pertuzumab 30 mg/ml (30,000 ppm)	>240
Raltitrexed 0.5 mg/ml (500 ppm)	>240
Retrovir 10.0 mg/ml (10,000 ppm)	>240
Rituximab 10 mg/ml (10,000 ppm)	>240
Temsirolimus 25.0 mg/ml (25,000 ppm)	>240
Thiotepa 10.0 mg/ml (10,000 ppm)	69.2 min
Topotecan HCl 1.0 mg/ml (1,000 ppm)	>240
Trastuzumab 21.0 mg/ml (21,000 ppm)	>240
Trisonex 1 mg/ml (1,000 ppm)	>240
Vinblastine 1 mg/ml (1,000 ppm)	>240
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240
Vinorelbine 10 mg/ml (10,000 ppm)	>240
Zoledronic Acid 0.8 mg/ml (800 ppm)	>240
Fentanyl Citrate, 100mcg/2mL	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 33.1 minutes
Thiotepa (10.0 mg/ml) 69.2 minutes

CAUTION: Testing showed an average breakthrough time of 33.1 minutes with Carmustine and 69.2 minutes with Thiotepa.

Indications for Use – Extended Cuff (VS711XS, VS711S, VS711M, VS711L and VS711XL)

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 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemo Drugs Tested:	Breakthrough Time (Minutes)
Aresenic Trioxide 1 mg/ml	>240
Azacitidine 25 mg/ml	>240
Bendamustine 5 mg/ml	>240
Bleomycin 15 mg/m	>240
Bortezomib 1 mg/ml	>240
Busulfan 6 mg/ml	>240

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Northfield, IL 60093

Carfilzomib 2 mg/ml	>240
Carmustine (BCNU) 3.3 mg/ml	59.4 min
Cetuximab	>240
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240
Cytarabine Hydrochloride 100 mg/ml	>240
Cytovene 10 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240
Daunorubicin 5 mg/ml	>240
Decitabine 5 mg/ml	>240
Docetaxel 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Epirubicin (Ellence) 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fludarabine 25 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Fulvestrant 50.0 mg/ml	>240
Gemcitabine (Gemzar) 38 mg/ml	>240
Idarubicin 1 mg/ml	>240
Irinotecan 20.0 mg/ml	>240
Mechlorethamine HCl 1.0 mg/ml	>240
Melphalan 5 mg/ml	>240
Methotrexate 25.0 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Oxaliplatin 5.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Paraplatin (Carboplatin) 10 mg/ml	>240
Pemetrexed Disodium 25.0 mg/ml	>240
Pertuzumab 30 mg/ml	>240
Raltitrexed 0.5 mg/ml	>240
Retrovir 10.0 mg/ml	>240
Rituximab 10 mg/ml	>240
Temsirolimus 25.0 mg/ml	>240
Thiotepa 10.0 mg/ml	68.2 min
Topotecan HCl 1.0 mg/ml	>240
Trastuzumab 21.0 mg/ml	>240
Trisonex 1 mg/ml	>240
Vinblastine 1 mg/ml	>240
Vincristine Sulfate 1.0 mg/ml	>240

Vinorelbine 10 mg/ml	>240
Zoledronic Acid 0.8 mg/ml	>240
Fentanyl Citrate, 100mcg/2mL	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 59.4 minutes
Thiotepa (10.0 mg/ml) 68.2 minutes

CAUTION: Testing showed an average breakthrough time of 59.4 minutes with Carmustine and 68.2 minutes with Thiotepa.

Comparison of Technological Characteristics

TABLE 3: Comparison of Proposed – VS311 and Predicate Device

Device Characteristic	Proposed Device VS311	Predicate Device	Comparison Analysis
Product Name	Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) Regular Cuff	Non-Sterile, Powder-Free Nitrile Examination Gloves (Cobalt)Tested for use with chemotherapy drugs	**N/A**
510(k) Reference	K193666	K111248	**N/A**
Product Owner	Medline Industries, Inc.	YTY Industry (Manjung) SDN, BHD	**N/A**
Product Code	LZA, OPJ, QDO	LZA, LZC	**Similar**

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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 and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. These glove were tested for use with chemotherapy drugs.	**Same**
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	**Same**
Materials	Powder-Free Nitrile	Powder-Free Nitrile	**Same**
Color	Blue	Blue	**Same**
Sizes	x- small, small, medium, large, x-large	Medium, Large, Extra-large	**Similar**
Dimensions – Length	Complies with: ASTM D6319-10 220mm min	Complies with: ASTM D6319-10 220mm min.	**Same**
Dimensions – Width	Complies with: ASTM D6319-10 70mm min	Complies with: ASTM D6319-10 70mm min	**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**

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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 2.5	**Same**
Powder or Powder-Free	Powder-Free	Powder-Free	**Same**
Residual Powder	Complies with: ASTM D6319-10 <2mg per glove	Complies with: ASTM D6319-05 <2mg per glove	**Same**
Contact Durations	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	**Same**
Sterility	Non-sterile	Non-sterile	**Same**
Rx Only or OTC	Over the Counter	Over the Counter	**Same**
Tested Chemotherapy Drugs	Aresenic Trioxide 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Azacitidine (Vidaza) 25.0 mg/ml (25,000 ppm) >240 min.		**Different**
	Bendamustine 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Bleomycin 15.0 mg/ml (15,000 ppm) >240 min.		**Different**
	Bortezomib 1.0 mg/ml (1,000 ppm) >240 min.		**Different**

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	Busulfan 6.0 mg/ml (6,000 ppm) >240 min.		**Different**
	Carboplatin 10mg/ml 10,000 ppm >240 min	Carboplatin 10mg/ml 10,000 ppm >240 min	**Same**
	Carfilzomib 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) 33.1 min.	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) 1.82 min	**Similar**
	Cetuximab 2.0 mg/ml (2,000 ppm) >240 min		**Different**
	Cisplatin 1.0 mg.ml (1,000 ppm) >240 min.	Cisplatin 1.0 mg/ml (1,000 ppm) >240 min.	**Same**
	Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm) >240 min.	Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm) >240 min.	**Same**
	Cytarabine 100.0 mg/ml (100,000 ppm) >240 min.		**Different**
	Cytovene 10.0 mg/ml (10,000 ppm) >240 min.		**Different**
	Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm) >240 min.	Dacarbazine (DTIC) 10 mg/ml (10,000 ppm) >240 min.	**Same**
	Daunorubicin 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Decitabine 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Docetaxel 10.0 mg/ml (10,000 ppm) >240 min.		**Different**

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	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) >240 min. *	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) >240 min	**Same**
	Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Etoposide (Toposar) 20.0 mg/ml (20,000 ppm) >240 min. *	Etoposide (Toposar) 20.0 mg/ml (20,000 ppm) >240 min.	**Same**
	Fludarabine 25.0 mg/ml (25,000 ppm) >240 min.		**Different**
	Fluorouracil 50.0 mg/ml (50,000 ppm) >240 min.	Fluorouracil 50.0 mg/ml (50,000 ppm) >240 min.	**Same**
	Fulvestrant 50.0 mg/ml (50,000 ppm) >240 min.		**Different**
	Gemcitabine (Gemzar) 38.0 mg/ml (38,000 ppm) >240 min.		**Different**
	Idarubicin 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Ifosfamide 50.0 mg/ml (50,000 ppm) >240 min.	Ifosfamide 50.0 mg/ml (50,000 ppm) >240 min.	**Same**
	Irinotecan 20.0 mg/ml (20,000 ppm) >240 min.		**Different**
	Mechlorethamine HCl 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Melphalan 5.0 mg/ml (5,000 ppm) >240 min.		**Different**

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	Methotrexate 25.0 mg/ml (25,000 ppm) >240 min. *	Methotrexate 25.0 mg/ml (25,000 ppm) >240 min.	**Same**
	Mitomycin C 0.5 mg/ml (500 ppm) >240 min.	Mitomycin C 0.5 mg/ml (2,000 ppm) >240 min.	**Same**
	Mitoxantrone 2.0 mg/ml (2,000 ppm) >240 min.	Mitoxantrone 2.0 mg/ml (2,000 ppm) >240 min.	**Same**
	Oxaliplatin 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) >240 min.	Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) >240 min.	**Same**
	Paraplatin 10.0 mg/ml (10,000 ppm) >240 min.		**Different**
	Pemetrexed Disodium 25.0 mg/ml (25,000 ppm) >240 min.		**Different**
	Pertuzumab 30.0 mg/ml (30,000 ppm) >240 min.		**Different**
	Raltitrexed 0.5 mg/ml (500 ppm) 240> min.		**Different**
	Retrovir 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Rituximab 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Temsirolimus 25.0 mg/ml (25,000 ppm) 240> min.		**Different**
	Thiotepa 10.0 mg/ml (10,000 ppm) 69.2 min.	Thiotepa 10.0 mg/ml (10,000 ppm) 0.93 min	**Similar**

	Topotecan HCl 1.0 mg/ml (1,000 ppm) 240> min.		**Different**
	Trastuzumab 21.0 mg/ml (21,000 ppm) 240> min.		**Different**
	Trisonex 1.0 mg/ml (1,000 ppm) 240> min.		**Different**
	Vinblastine 1 mg/ml (1,000 ppm) 240> min.		**Different**
	Vincristine Sulfate 1.0 mg/ml (1,000 ppm) >240 min.	Vincristine Sulfate 1.0 mg/ml (1,000 ppm) >240 min.	**Same**
	Vinorelbine 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Zoledronic Acid 0.8 mg/ml (800 ppm) 240> min.		**Different**
Fentanyl Testing	Fentanyl Citrate, 100.0 mcg/2mL >240 min.		**Different**

TABLE 4: Comparison of Proposed – VS711 and Predicate Device

Device Characteristic	Proposed Device VS711	Predicate Device	Comparison Analysis
Product Name	Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) Extended Cuff	Non-Sterile, Powder-Free Nitrile Examination Gloves (Cobalt)Tested for use with chemotherapy drugs	**N/A**
510(k) Reference	K193666	K111248	**N/A**
Product Owner	Medline Industries, Inc.	YTY Industry (Manjung) SDN, BHD	**N/A**
Product Code	LZA, OPJ, QDO	LZA, LZC	**Similar**

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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 and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. These glove were tested for use with chemotherapy drugs.	**Same**
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	**Same**
Materials	Powder-Free Nitrile	Powder-Free Nitrile	**Same**
Color	Blue	Blue	**Same**
Sizes	x- small, small, medium, large, x-large	Medium, Large, Extra-large	**Similar**
Dimensions – Length	Complies with: ASTM D6319-10 230mm min	Complies with: ASTM D6319-10 230mm min.	**Same**

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Dimensions – Width	Complies with: ASTM D6319-10 70mm min	Complies with: ASTM D6319-10 70mm min	**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 2.5	**Same**
Powder or Powder-Free	Powder-Free	Powder-Free	**Same**
Residual Powder	Complies with: ASTM D6319-10 <2mg per glove	Complies with: ASTM D6319-05 <2mg per glove	**Same**
Contact Durations	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	**Same**
Sterility	Non-sterile	Non-sterile	**Same**
Rx Only or OTC	Over the Counter	Over the Counter	**Same**
Tested Chemotherapy Drugs	Aresenic Trioxide 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Azacitidine (Vidaza) 25.0 mg/ml (25,000 ppm) >240 min.		**Different**

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	Bendamustine 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Bleomycin 15.0 mg/ml (15,000 ppm) >240 min.		**Different**
	Bortezomib 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Busulfan 6.0 mg/ml (6,000 ppm) >240 min.		**Different**
	Carboplatin 10mg/ml 10,000 ppm >240 min	Carboplatin 10mg/ml 10,000 ppm >240 min	**Same**
	Carfilzomib 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) 59.4 min.	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) 1.82 min	**Similar**
	Cetuximab 2.0 mg/ml (2,000 ppm) >240 min		**Different**
	Cisplatin 1.0 mg.ml (1,000 ppm) >240 min.	Cisplatin 1.0 mg/ml (1,000 ppm) >240 min.	**Same**
	Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm) >240 min.	Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm) >240 min.	**Same**
	Cytarabine 100.0 mg/ml (100,000 ppm) >240 min.		**Different**
	Cytovene 10.0 mg/ml (10,000 ppm) >240 min.		**Different**
	Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm) >240 min.	Dacarbazine (DTIC) 10 mg/ml (10,000 ppm) >240 min.	**Same**

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	Daunorubicin 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Decitabine 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Docetaxel 10.0 mg/ml (10,000 ppm) >240 min.		**Different**
	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) >240 min. *	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) >240 min	**Same**
	Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Etoposide (Toposar) 20.0 mg/ml (20,000 ppm) >240 min. *	Etoposide (Toposar) 20.0 mg/ml (20,000 ppm) >240 min.	**Same**
	Fludarabine 25.0 mg/ml (25,000 ppm) >240 min.		**Different**
	Fluorouracil 50.0 mg/ml (50,000 ppm) >240 min.	Fluorouracil 50.0 mg/ml (50,000 ppm) >240 min.	**Same**
	Fulvestrant 50.0 mg/ml (50,000 ppm) >240 min.		**Different**
	Gemcitabine (Gemzar) 38.0 mg/ml (38,000 ppm) >240 min.		**Different**
	Idarubicin 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Irinotecan 20.0 mg/ml (20,000 ppm) >240 min.		**Different**

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	Mechlorethamine HCl 1.0 mg/ml (1,000 ppm) >240 min.		**Different**
	Melphalan 5.0 mg/ml (5,000 ppm) >240 min.		**Different**
	Methotrexate 25.0 mg/ml (25,000 ppm) >240 min. *	Methotrexate 25.0 mg/ml (25,000 ppm) >240 min.	**Same**
	Mitomycin C 0.5 mg/ml (500 ppm) >240 min.	Mitomycin C 0.5 mg/ml (2,000 ppm) >240 min.	**Same**
	Oxaliplatin 2.0 mg/ml (2,000 ppm) >240 min.		**Different**
	Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) >240 min.	Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) >240 min.	**Same**
	Paraplatin 10.0 mg/ml (10,000 ppm) >240 min.		**Different**
	Pemetrexed Disodium 25.0 mg/ml (25,000 ppm) >240 min.		**Different**
	Pertuzumab 30.0 mg/ml (30,000 ppm) >240 min.		**Different**
	Raltitrexed 0.5 mg/ml (500 ppm) 240> min.		**Different**
	Retrovir 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Rituximab 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Temsirolimus 25.0 mg/ml (25,000 ppm) 240> min.		**Different**

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	Thiotepa (THT) 10.0 mg/ml (10,000 ppm) 68.2 min.	Thiotepa 10.0 mg/ml (10,000 ppm) 0.93 min	**Similar**
	Topotecan HCl 1.0 mg/ml (1,000 ppm) 240> min.		**Different**
	Trastuzumab 21.0 mg/ml (21,000 ppm) 240> min.		**Different**
	Trisonex 1.0 mg/ml (1,000 ppm) 240> min.		**Different**
	Vinblastine 1 mg/ml (1,000 ppm) 240> min.		**Different**
	Vincristine Sulfate 1.0 mg/ml (1,000 ppm) >240 min.	Vincristine Sulfate 1.0 mg/ml (1,000 ppm) >240 min.	**Same**
	Vinorelbine 10.0 mg/ml (10,000 ppm) 240> min.		**Different**
	Zoledronic Acid 0.8 mg/ml (800 ppm) 240> min.		**Different**
Fentanyl Testing	Fentanyl Citrate, 100.0 mcg/2mL >240 min.		**Different**

Summary of Non-Clinical Testing:

Biocompatibility Testing

Table 5 below summarize the biocompatibility results for the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and the Medline Powder-Free Blue Nitrile Examination Gloves-(Tested for use with Chemotherapy Drugs and Fentanyl) – Extended Cuff

Table 5: Biocompatibility Testing – VS311 & VS711

Name of Test /Citation	Purpose	Acceptance Criteria	Results
ISO 10993-10: 2010 Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Skin Sensitization	Irritation Testing	Pass/Fail	Pass Under the conditions of the study, the subject device is not a primary skin irritant.
ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.	Sensitization Testing	Pass/Fail	Pass Under the conditions of the study, the subject device is not a primary skin sensitizer.
ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity	Cytotoxicity Testing	Pass/Fail	Failed Under the conditions of the study, the subject device is cytotoxic.
ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.	Systemic Toxicity Testing	Pass/Fail	Pass Under the conditions of the study, the subject device is not toxic.

Table 6: Quality Assurance Testing For Finished Gloves

Characteristics	Reference Test Method & Sampling	Inspection Level	Inspection Level	Acceptance Criteria
Dimension (length, width, thickness)	ASTM D6319 – 10 (2015)	S-2	4.0	Meet Acceptance Number
Tensile strength and Ultimate elongation	ASTM D 6319 – 10 (2015)	S-2	4.0	Meet Acceptance Number
Water Leak	ASTM D 5151-06 (2015) and ASTM D 6319-10	G-1	1.5	Meet Acceptance Number
Powder Residue	ASTM D6124 - 06 (2011)	N/A	N/A	2 mg/glove

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Physical Dimensions

Thirteen (13) glove samples of each size (extra-small, small, medium, large and extra-large) were tested for physical dimensions according to ASTM D6319-10. All samples from each of the five size gloves met the specifications for physical dimensions.

Tables 7 through 16 below summarize the physical dimension results for the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff.

TABLE 7: ASTM D6319-10 Test Results – Extra-Small, VS311XS (Regular Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	220mm min.	247mm	Yes
Palm Width	70 ± 10mm	78mm	Yes
Thickness Finger	0.05mm min.	0.16mm	Yes
Thickness Palm	0.05mm min.	0.11mm	Yes

TABLE 8: ASTM D6319-10 Test Results – Small, VS311S (Regular Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	220mm min.	248mm	Yes
Palm Width	80 ± 10mm	86mm	Yes
Thickness Finger	0.05mm min	0.16mm	Yes
Thickness Palm	0.05mm min	0.11mm	Yes

TABLE 9: ASTM D6319-10 Test Results – Medium, VS311M (Regular Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	250mm	Yes
Palm Width	95 ± 10mm	97mm	Yes
Thickness Finger	0.05mm	0.15mm	Yes
Thickness Palm	0.05mm	0.11mm	Yes

TABLE 10: ASTM D6319-10 Test Results – Large, VS311L (Regular Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	250mm	Yes
Palm Width	110 ± 10mm	107mm	Yes
Thickness Finger	0.05mm	0.16mm	Yes
Thickness Palm	0.05mm	0.11mm	Yes

TABLE 11: ASTM D6319-10 Test Results – Extra-Large, VS311XL (Regular Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	251mm	Yes
Palm Width	120 ± 10mm	119mm	Yes
Thickness Finger	0.05mm	0.15mm	Yes
Thickness Palm	0.05mm	0.11mm	Yes

TABLE 12: ASTM D6319-10 Test Results – Extra-Small, VS711XS (Extended Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	220mm min.	302mm	Yes
Palm Width	70 ± 10mm	78mm	Yes
Thickness Finger	0.05mm min.	0.17mm	Yes
Thickness Palm	0.05mm min.	0.12mm	Yes

TABLE 13: ASTM D6319-10 Test Results – Small, VS711S (Extended Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	220mm	300mm	Yes
Palm Width	80 ± 10mm	89mm	Yes
Thickness Finger	0.05mm min.	0.18mm	Yes
Thickness Palm	0.05mm min.	0.12mm	Yes

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TABLE 14: ASTM D6319-10 Test Results – Medium, VS711M (Extended Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	301mm	Yes
Palm Width	95 ± 10mm	99mm	Yes
Thickness Finger	0.05mm	0.18mm	Yes
Thickness Palm	0.05mm	0.13mm	Yes

TABLE 15: ASTM D6319-10 Test Results – Large, VS711L (Extended Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	299mm	Yes
Palm Width	110 ± 10mm	108mm	Yes
Thickness Finger	0.05mm	0.16mm	Yes
Thickness Palm	0.05mm	0.12mm	Yes

TABLE 16: ASTM D6319-10 Test Results – Extra-Large, VS711XL (Extended Cuff)

Characteristic	Device Specification	Average Device Performance (n=13)	Complies with Standard (Y/N)
Glove Length	230mm min.	298mm	Yes
Palm Width	120 ± 10mm	115mm	Yes
Thickness Finger	0.05mm	0.18mm	Yes
Thickness Palm	0.05mm	0.23mm	Yes

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Freedom from Holes

Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff were tested for freedom from holes as per ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves and the FDA 1000ml Water Leak Test per 21 CFR 800.20. The results for all sizes (XS/S/M/L/XL) are summarized in Tables below.

TABLE 17: ASTM D5151 Freedom from Holes Test Results: PF Blue Nitrile Glove – Regular Cuff (VS311)

Characteristic	Specification	Device Performance	Complies with Standard (Y/N)
Freedom from Holes	ASTM D 5151-06 (2015) and ASTM D 6319-10, G-1, AQL 1.5	XS/Small/Medium – 1/200 Large – 4/400 X-Large -2/200	Y

TABLE 18: ASTM D5151 Freedom from Holes Test Results: PF Blue Nitrile Glove-Extended Cuff (VS711)

Characteristic	Specification	Device Performance	Complies with Standard (Y/N)
Freedom from Holes	ASTM D 5151-06 (2015) and ASTM D 6319-10, G-1, AQL 1.5	XS/Small/Medium, Large, X-Large -0/200	Y

Powder Content

Residual powder content for the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff was confirmed in accordance with ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves. The average results for all sizes (XS/S/M/L/XL) are summarized below.

TABLE 19: ASTM D6124 Residual Powder Test Results: PF Blue Nitrile Glove – Regular Cuff (VS311)

Characteristic	Specification	Device Performance	Complies with Standard (Y/N)
Powder Content per Glove	Less Than 2mg/glove	X-Small – 0.16 mg/glove Small – 0.20 mg/glove Medium – 0.16 mg/glove Large – 0.16 mg/glove X-Large – 0.18 mg/glove	Y

TABLE 20: ASTM D6124 Residual Powder Test Results: PF Blue Nitrile Glove-Extended Cuff (VS711)

Characteristic	Specification	Device Performance	Complies with Standard (Y/N)
Powder Content per Glove	Less Than 2mg/glove	X-Small- 0.16 Small- 0.20 Medium- 0.16 Large- 0.18 X-Large- 0.18	Y

Permeation Testing

Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs and Fentanyl. 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 and Fentanyl. A summary of the minimum breakthrough times is provided in Table 21 and Table 22 (below).

Please note that the following drug, Carmustine and Thiotepa have a low permeation time. Labeling will include caution statement in the presence of these chemotherapy drugs.

TABLE 21: Chemotherapy Drugs/Fentanyl Tested – Regular Cuff (VS311XS, VS311S, VS311M, VS311L and VS311XL)

Summarized in Table 21 below are the drugs the proposed devices have been tested for use with per ASTM D6978-05 (Reapproved 2019) *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*.

Chemotherapy Drug Tested	Breakthrough Time(minutes)
Aresenic Trioxide 1 mg/ml (1,000 ppm)	>240
Azacitidine 25 mg/ml (25,000 ppm)	>240
Bendamustine 5 mg/ml (5,000 ppm)	>240
Bleomycin 15 mg/ml (15,000 ppm)	>240
Bortezomib 1 mg/ml (1,000 ppm)	>240
Busulfan 6 mg/ml (6,000 ppm)	>240
Carboplatin 10.0 mg/ml (10,000 ppm)	>240

Carfilzomib 2.0 mg/ml (2,000)	>240
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	33.1 min
Cetuximab 2.0 mg/ml (2,000)	>240
Cisplatin 1.0 mg/ml (1,000 ppm)	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	>240
Cytarabine 100 mg/ml (100,000 ppm)	>240
Cytovene 10 mg/ml (10,000 ppm)	>240
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	>240
Daunorubicin 5 mg/ml (5,000 ppm)	>240
Decitabine 5 mg/ml (5,000 ppm)	>240
Docetaxel 10.0 mg/ml (10,000 ppm)	>240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	>240
Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm)	>240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	>240
Fludarabine 25 mg/ml (25,000 ppm)	>240
Fluorouracil 50.0 mg/ml (50,000 ppm)	>240
Fulvestrant 50.0 mg/ml (50,000 ppm)	>240
Gemcitabine (Gemzar) 38 mg/ml (38,000 ppm)	>240
Idarubicin 1 mg/ml (1,000 ppm)	>240
Ifosfamide 50.0 mg/ml (50,000 ppm)	>240
Irinotecan 20.0 mg/ml (20,000 ppm)	>240
Mechlorethamine HCl 1.0 mg/ml (1,000 ppm)	>240
Melphalan 5 mg/ml (5,000 ppm)	>240
Methotrexate 25 mg/ml (25,000 ppm)	>240
Mitomycin C 0.5 mg/ml (500 ppm)	>240
Mitoxantrone 2.0 mg/ml (2,000 ppm)	>240
Oxaliplatin 2.0 mg/ml (2,000 ppm)	>240
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	>240
Paraplatin 10 mg/ml (10,000 ppm)	>240
Pemetrexed Disodium 25.0 mg/ml (25,000 ppm)	>240
Pertuzumab 30 mg/ml (30,000 ppm)	>240

Raltitrexed 0.5 mg/ml (500 ppm)	>240
Retrovir 10.0 mg/ml (10,000 ppm)	>240
Rituximab 10 mg/ml (10,000 ppm)	>240
Temsirolimus 25.0 mg/ml (25,000 ppm)	>240
Thiotepa 10.0 mg/ml (10,000 ppm)	69.2 min
Topotecan HCl 1.0 mg/ml (1,000 ppm)	>240
Trastuzumab 21.0 mg/ml (21,000 ppm)	>240
Trisonex 1 mg/ml (1,000 ppm)	>240
Vinblastine 1 mg/ml (1,000 ppm)	>240
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240
Vinorelbine 10 mg/ml (10,000 ppm)	>240
Zoledronic Acid 0.8 mg/ml (800 ppm)	>240
Fentanyl Tested	**Breakthrough Time (in minutes)**
Fentanyl Citrate, 100mcg/2mL	>240

TABLE 22: Chemotherapy/Fentanyl Drugs Tested – Extended Cuff (VS311XS, VS311S, VS311M, VS311L and VS311XL)

Summarized in 18 below, are the drugs the proposed devices have been tested for use with per ASTM D6978-05 (Reapproved 2019) *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*.

Chemotherapy Drug Tested	Breakthrough Time (in minutes)
Aresenic Trioxide 1 mg/ml	>240
Azacitidine 25 mg/ml	>240
Bendamustine 5 mg/ml	>240
Bleomycin 15 mg/m	>240
Bortezomib 1 mg/ml	>240
Busulfan 6 mg/ml	>240
Carfilzomib 2 mg/ml	>240
Carmustine (BCNU) 3.3 mg/ml	59.4 min
Cetuximab	>240
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20.0 mg/ml	>240
Cytarabine Hydrochloride 100 mg/ml	>240
Cytovene 10 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240

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Three Lakes Drive
Northfield, IL 60093

Daunorubicin 5 mg/ml	>240
Decitabine 5 mg/ml	>240
Docetaxel 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Epirubicin (Ellence) 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fludarabine 25 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Fulvestrant 50.0 mg/ml	>240
Gemcitabine (Gemzar) 38 mg/ml	>240
Idarubicin 1 mg/ml	>240
Irinotecan 20.0 mg/ml	>240
Mechlorethamine HCl 1.0 mg/ml	>240
Melphalan 5 mg/ml	>240
Methotrexate 25.0 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Oxaliplatin 5.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Paraplatin (Carboplatin) 10 mg/ml	>240
Pemetrexed Disodium 25.0 mg/ml	>240
Pertuzumab 30 mg/ml	>240
Raltitrexed 0.5 mg/ml	>240
Retrovir 10.0 mg/ml	>240
Rituximab 10 mg/ml	>240
Temsirolimus 25.0 mg/ml	>240
Thiotepa 10.0 mg/ml	68.2 min
Topotecan HCl 1.0 mg/ml	>240
Trastuzumab 21.0 mg/ml	>240
Trisonex 1 mg/ml	>240
Vinblastine 1 mg/ml	>240
Vincristine Sulfate 1.0 mg/ml	>240
Vinorelbine 10 mg/ml	>240
Zoledronic Acid 0.8 mg/ml	>240
Fentanyl Tested	**Breakthrough Time (in minutes)**
Fentanyl Citrate, 100mcg/2mL	>240

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 Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff and the Medline Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff are as safe, as effective, and performs as well as or better than the legally marketed predicate device, the YTY Industry (Manjung) Non-Sterile, Powder-Free Nitrile Examination Gloves (Cobalt Blue) Tested for use with Chemotherapy Drugs – K111248.