June 3, 2025

Glove One, LLC
% Terrie Heidemann
Consultant
Terrie M Heidemann
3085 N Broadway
Escondido, California 92026

Re: K243796
Trade/Device Name: GLOVEONE™ Powder-Free Nitrile Examination Gloves - Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: April 28, 2025
Received: May 1, 2025

Dear Terrie Heidemann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243796

Device Name
GLOVEONE™ Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]

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 and fentanyl citrate per ASTM D6978-05 (Reapproved 2019) Standard Practices for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Tested	Breakthrough Time (minutes)
Cisplatin 1 mg/ml (1,000 ppm)	>240 min
Cyclophosphamide 20 mg/ml (20,000 ppm)	>240 min
Dacarbazine 10 mg/ml (10,000 ppm)	>240 min
Doxorubicin HCL 2 mg/ml (2,000 ppm)	>240 min
Etoposide 20 mg/ml (20,000 ppm)	>240 min
Fluorouracil 50 mg/ml (50,000 ppm)	>240 min
Ifosamide 50 mg/ml (50,000 ppm)	>240 min
Mitroxantrone HCL 2 mg/ml (2,000 ppm)	>240 min
Paclitaxel 6 mg/ml (16,000 ppm)	>240 min
Vincristine Sulfate 1 mg/ml (1,000 ppm)	>240 min
Carmustine 3.3 mg/ml (3,000 ppm)	12.3 minutes
Thiotepa 10 mg/ml (10,000 ppm) > 240 min	13.4 minutes

Fentanyl Tested	Breakthrough Time (minutes)
Fentanyl Citrate Injection, 100 mcg/2 mL	>240 min

WARNING: The following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 12.3 minutes
Thiotepa (THT) (10.0 mg/ml) 13.4 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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510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

GLOVEONE, LLC
205 Raceway Drive Suite 3
Mooresville, NC 28117
Applicant Contact: Terrie Heidemann, Regulatory Affairs
3085 N Broadway
Escondido, CA 92026 USA
+1.760.855.0613
terriemheidemann@gmail.com

Summary Preparation Date:29May2025

Type of 510(k) Submission
Traditional

Device Classification: Class I

510(k) Number: K243796

Device Name/Classification
Name of Device: GLOVEONE™ Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]
Common Name: Patient Examination Glove, Specialty
Classification Name: Polymer Patient Exam Glove, Medical Gloves with Chemotherapy/Fentanyl Labeling Claims
Product Code: LZA, LZC, OPJ, QDO
Classification Panel: General Hospital
Regulation #: 21 CFR 880.6250

Predicate Device
Medline Powder-Free Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl)- Regular Cuff – K193666
Product Code: LZA, OPJ, QDO
Applicant Name:
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Device Description

GLOVEONE™, Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for Use with Chemotherapy Drugs and Fentanyl] are Class I patient examination gloves, bearing the product codes LZA, LZC, OPJ, QDO (21 CFR 880.6250). They meet all current specifications listed under the ASTM D6319-19 (2023), Standard Specification for Nitrile Examination Gloves for Medical Application and comply with requirements for Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs per ASTM D6978-05. The powder-free gloves are made from Nitrile (NBR) latex and are green in color. The product is non-sterile, fingertip textured, ambidextrous with beaded cuff, and single use only. The product is not manufactured using natural rubber latex.

GLOVEONE™, Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for Use with Chemotherapy Drugs and Fentanyl] include glove sizes: X-Small, Small, Medium, Large, and X- Large.

Table 1: GLOVEONE™ Powder-Free Nitrile Examination Gloves

Glove Type	Model Number	Size	Glove Count
GLOVEONE™ Powder Free, Nitrile Exam Glove – Non-sterile	GO1111-100	Extra-Small	100
	GO1111-200		200
	GO1112-100	Small	100
	GO1112-200		200
	GO1113-100	Medium	100
	GO1113-200		200
	GO1114-100	Large	100
	GO1114-200		200
	GO1115-100	Extra-Large	100
	GO1115-200		200

The gloves are designed and manufactured in accordance with the ASTM D6319-19 (2023) 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).

Physical Description

GLOVEONE™ (Green Colored), Nitrile, powder free, non-sterile, textured fingertips, ambidextrous, beaded cuff, examination gloves with online chlorination on the grip side.

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 and fentanyl citrate per ASTM D6978-05 (Reapproved 2019) Standard Practices for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Tested	Breakthrough Time (minutes)
Cisplatin 1 mg/ml (1,000 ppm)	> 240 min
Cyclophosphamide 20 mg/ml (20,000 ppm)	> 240 min
Dacarbazine 10 mg/ml (10,000 ppm)	> 240 min
Doxorubicin HCL 2 mg/ml (2,000 ppm)	> 240 min
Etoposide 20 mg/ml (20,000 ppm)	> 240 min
Fluorouracil 50 mg/ml (50,000 ppm)	> 240 min
Ifosamide 50 mg/ml (50,000 ppm)	> 240 min
Mitroxantrone HCL 2 mg/ml (2,000 ppm)	> 240 min
Paclitaxel 6 mg/ml (16,000 ppm)	> 240 min
Vincristine Sulfate 1 mg/ml (1,000 ppm)	>240 min
Carmustine 3.3 mg/ml (3,000 ppm)	12.3 minutes (21.2, 12.8, 12.6)
Thiotepa 10 mg/ml (10,000 ppm)	13.4 minutes (17.1, 15.4, 13.4)

Fentanyl Tested	Breakthrough Time (minutes)
Fentanyl Citrate Injection, 100 mcg/2 mL	>240 min

**WARNING: Not for use with Carmustine or Thiotepa

The following drugs have low permeation times:

Carmustine (BCNU) (3.3 mg/ml) 12.3 minutes

Thiotepa (THT) (10.0 mg/ml) 13.4 minutes

Comparison of Technological Characteristics

Device Characteristics	Proposed Device	Medline Predicate Device	Comparison Analysis
Product Name	GLOVEONE™, Powder Free, Nitrile Examination Glove – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]	Medline Powder-Free Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) – Regular Cuff	**N/A**
510(k)	K243796	K193666	**N/A**
Product Owner	GLOVEONE™	Medline Industries, Inc.	**N/A**
Product Code	LZA, LZC, OPJ, QDO	LZA, OPJ, QDO	**Similar**
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 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 and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) 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	Powder-Free Nitrile	Powder-Free Nitrile	**Same**
Color	Green	Blue	**Similar**
Sizes	xs-small, small, medium, large, x-large	xs-small, small, medium, large, x-large	**Same**
Dimensions – Length	Complies with: ASTM D6319-19 (2023) 220mm min	Complies with: ASTM D6319-10 220mm min	**Same**
Dimensions – Width	Complies with: ASTM D6319-19 (2023) 70mm min	Complies with: ASTM D6319-10 70mm min	**Same**
Dimensions – Thickness	Complies with: ASTM D6319-19 (2023) Palm – 0.05 mm min Finger – 0.05mm min	Complies with: ASTM D6319-10 Palm – 0.05 mm min Finger – 0.05mm min	**Same**
Physical Properties	Complies with: ASTM D6319-19 (2023) minimum Tensile Strength: Before Aging ≥ 14 MPa, min After Aging ≥ 14 MPa, Min Elongation:	Complies with: ASTM D6319-10 minimum Tensile Strength: Before Aging ≥ 14 MPa, min After Aging ≥ 14 MPa, Min Elongation:	**Same**

Device Characteristics	Proposed Device	Medline Predicate Device	Comparison Analysis
	Before Aging 500% min. After Aging 400%, min.	Before Aging 500% min. After Aging 400%, min.	
Freedom from Holes	Complies with: ASTM D6319-19 (2023) and ASTM D5151-19 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 D6319-19 (2023) ≤ 2 mg per glove	Complies with: ASTM D6319-10 ≤ 2 mg per glove	**Same**
Contact Durations	Limited ≤ 24 hours	Limited ≤ 24 hours	**Same**
Biocompatibility	AAMI/ANSI/ISO 10993-11: Under the conditions of the study, the subject device is not acutely toxic.	AAMI/ANSI/ISO 10993-11: Under the conditions of the study, the subject device is not acutely toxic.	**Same**
	AAMI/ANSI/ISO 10993-10: Under the conditions of the study, the subject device is not a primary skin sensitizer.	AAMI/ANSI/ISO 10993-10: Under the conditions of the study, the subject device is not a primary skin sensitizer.	
	AAMI/ANSI/ISO 10993-23: Under the conditions of the study, the subject device is not a primary skin irritant.	AAMI/ANSI/ISO 10993-10: Under the conditions of the study, the subject device is not a primary skin irritant.	
	AAMI/ANSI/ISO 10993-05: Under the conditions of the study, the subject device is cytotoxic.	AAMI/ANSI/ISO 10993-05: Under the conditions of the study, the subject device is cytotoxic.	
Sterility	Non-sterile	Non-sterile	**Same**
Rx Only or OTC	Over the Counter	Over the Counter	**Same**

Tested Chemotherapy Drugs and Fentanyl Citrate	• Cisplatin 1 mg/ml (1,000 ppm) • Cyclophosphamide 20 mg/ml (20,000 ppm) • Dacarbazine 10 mg/ml (10,000 ppm) • Doxorubicin HCL 2 mg/ml (2,000 ppm) • Etoposide 20 mg/ml (20,000 ppm) • Fluorouracil 50 mg/ml (50,000 ppm) • Ifosamide 50 mg/ml (50,000 ppm) • Mitroxantrone HCL 2	• Cisplatin 1 mg/ml (1,000 ppm) • Cyclophosphamide 20 mg/ml (20,000 ppm) • Dacarbazine 10 mg/ml (10,000 ppm) • Doxorubicin HCL 2 mg/ml (2,000 ppm) • Etoposide 20 mg/ml (20,000 ppm) • Fluorouracil 50 mg/ml (50,000 ppm) • Ifosamide 50 mg/ml (50,000 ppm) • Mitroxantrone HCL 2	**Similar**

Device Characteristics	Proposed Device	Medline Predicate Device	Comparison Analysis
	mg/ml (2,000 ppm) • Paclitaxel 6 mg/ml (16,000 ppm) • Vincristine Sulfate 1 mg/ml (1,000 ppm) • Carmustine 3.3 mg/ml (3,000 ppm) • Thiotepa 10 mg/ml (10,000 ppm) • Fentanyl Citrate Injection 100 mcg/2 ml	mg/ml (2,000 ppm) • Paclitaxel 6 mg/ml (16,000 ppm) • Vincristine Sulfate 1 mg/ml (1,000 ppm) • Carmustine 3.3 mg/ml (3,000 ppm) • Thiotepa 10 mg/ml (10,000 ppm) • Fentanyl Citrate Injection 100 mcg/2 ml ***Medline evaluated 38 additional drugs which are not being claimed as part of the GLOVEONE™ submission*** • Arsenic Trioxide 1.0 mg/ml (1,000 ppm) • Azacitidine (Vidaza) 25.0 mg/ml (25,000 ppm0 • Bendamustine 5.0 mg/ml (5,000 ppm) • Bleomycin 15.0 mg/ml (15,000 ppm) • Bortezomib 1.0 mg/ml (1,000 ppm) • Busulfan 6.0 mg/ml (6,000 ppm) • Carboplatin 10 mg/ml (10,000 ppm) • Carfilzomib 2.0 mg/ml (2,000 ppm) • Cetuximab 2.0 mg/ml (2,000 ppm) • Cytarabine 100.0 mg/ml (100,000 ppm) • Cytovene 10.0 mg/ml (10,000 ppm) • Daunorubicin 5.0 mg/ml (5,000 ppm) • Decitabine 5.0 mg/ml (5,000 ppm)	

Device Characteristics	Proposed Device	Medline Predicate Device	Comparison Analysis
		• Docetaxel 10.0 mg/ml (10,000 ppm) • Epirubicin (Ellence) 2.0 mg/ml (2,000 ppm) • Fludarabine 25.0 mg/ml (25,000 ppm) • Fulvestrant 50.0 mg/ml (50,000 ppm) • Gemcitabine (Gemzar) 38.0 mg/ml (38,000 ppm) • Idarubicin 1.0 mg/ml (1,000 ppm) • Irinotecan 20.0 mg/ml (20,000 ppm) • Mechlorethamine HCL 1.0 mg/ml (1,000 ppm) • Melphalan 5.0 mg/ml (5,000 ppm) • Methotrexate 25.0 mg/ml (25,000 ppm) • Mitomycin C 0.5 mg/ml (50 ppm) • Oxaliplatin 2.0 mg/ml (2,000 ppm) • Paraplatin 10.0 mg/ml (10,000 ppm) • Pemetrexed Disodium 25.0 mg/ml (25,000 ppm) • Pertuzumab 30.0 mg/ml (30,000 ppm) • Raltitrexed 0.5 mg/ml (500 ppm) • Retrovir 10 mg/ml (10,000 ppm) • Rituximab 10 mg/ml (10,000 ppm) • Temsirolimus 25.0 mg/ml (25,000 ppm) • Topotecan HCl 1.0 mg/ml (1,000 ppm) • Trastuzumab 21.0 mg/ml (21,000 ppm) • Trisonex 1.0 mg/ml (1,000 ppm) • Vinblastine 1 mg/ml	

Device Characteristics	Proposed Device	Medline Predicate Device	Comparison Analysis
		(1,000 ppm) • Vinorelbine 10 mg/ml (10,000 ppm) • Zoledronic Acid 0.8 mg/ml (800 ppm)	

Summary of non-clinical testing

Biocompatibility Testing

Name of Test/Citation	Purpose	Acceptance Criteria	Results
ISO 10993-23: 2021 Biological Evaluation of Medical Devices, Part 23 – Tests for Irritation	Irritation Testing	Pass/Fail	Pass Under the conditions of the study, the subject device is not a primary skin irritant
ISO 10993-10:2021 Biological Evaluation of Medical Devices Part 10: Test for 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: Test for Systemic Toxicity	Acute Systemic Toxicity Testing	Pass/Fail	Pass Under the conditions of the study, the subject device does not exhibit acute systemic toxicity

Specification Performance Testing

Characteristics	Reference Test Method & Sampling	Inspection Level	Acceptance Criteria	Results
Dimension (length, width, thickness)	ASTM D6319-19 (2023)	S-2	AQL 4.0	Pass
Tensile strength and Ultimate Elongation	ASTM D6319-19 (2023)	S-2	AQL 4.0	Pass
Water Leak	ASTM D5151-19 (2023) and ASTM D6319-19 (2023)	G-1	AQL 2.5	Pass
Powder Residue	ASTM D6124-06 (2022)	N/A	< 2 mg/glove	Pass

Physical Dimensions

The table below summarizes the physical dimension results for the GLOVEONE™, Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl]

ASTM D6319-19 (2023) Test Results

Characteristics	Device Specification	Complies with Standard (Y/N)
Glove Length	x-small – ≥220 mm small – ≥ 220 mm medium – ≥230 mm large – ≥ 230 mm x-large – ≥230 mm	Yes
Palm Width	x-small – 70 mm small – 80 mm medium – 95 mm large – 110 mm x-large – 120 mm Tolerance (± 10 mm)	Yes
Thickness Finger	0.05 mm min.	Yes
Thickness Palm	0.05 mm min	Yes

Freedom from Holes

Glove samples of each size (extra-small, small, medium, large, and extra-large) were tested for freedom from holes as per ASTM D5151-19, 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.

Characteristics	Specification	Device Performance	Complies with Standard (Y/N)
Freedom from Holes	ASTM D5151-19 and ASTM D 6319-19 (2023), G-1 AQL 2.5	0 failures observed	Yes

Powder Content

Glove samples of the medium size were tested for powder content as per ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves. The average results are summarized below:

Characteristics	Specification	Device Performance	Complies with Standard (Y/N)
Powder Content per Glove	Less than 2 mg/glove	Less than 2 mg/glove	Yes

Permeation Testing

Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. The gloves were tested according to ASTM D6978, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum breakthrough times were determined for a wide range of chemotherapy drugs and for permeation of Fentanyl Citrate Injection. A summary of the minimum breakthrough times is provided in Tables below.

Chemotherapy Drugs Tested

Summarized in Table 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)
Cisplatin 1 mg/ml (1,000 ppm)	> 240 min
Cyclophosphamide 20 mg/ml (20,000 ppm)	> 240 min
Dacarbazine 10 mg/ml (10,000 ppm)	> 240 min
Doxorubicin HCL 2 mg/ml (2,000 ppm)	> 240 min
Etoposide 20 mg/ml (20,000 ppm)	> 240 min
Fluorouracil 50 mg/ml (50,000 ppm)	> 240 min
Ifosamide 50 mg/ml (50,000 ppm)	> 240 min
Mitroxantrone HCL 2 mg/ml (2,000 ppm)	> 240 min
Paclitaxel 6 mg/ml (16,000 ppm)	> 240 min
Vincristine Sulfate 1 mg/ml (1,000 ppm)	>240 min
Carmustine 3.3 mg/ml (3,000 ppm)	12.3 minutes (21.2, 12.8, 12.6)
Thiotepa 10 mg/ml (10,000 ppm)	13.4 minutes (17.1, 15.4, 13.4)

Fentanyl Tested	Breakthrough Time (minutes)
Fentanyl Citrate Injection, 100 mcg/2 mL	> 240 min

Summary of Clinical Testing

Clinical testing is not required for this device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the GLOVEONE™ Powder-Free Nitrile Examination Gloves – Non-sterile [Tested for use with Chemotherapy Drugs and Fentanyl] are as safe, as effective and performs as well as or better than the legally marketed predicate device.