July 4, 2023

US Glove Supply
% Prithul Bom
Accredited Person, Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K231740
Trade/Device Name: Memorial™ Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: June 14, 2023
Received: June 14, 2023

Dear Prithul Bom:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231740

Device Name

MemorialTM Gloves

Indications for Use *(Describe)*

These Powder Free, Nitrile Examination Gloves are a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection time
Cyclophosphamide (20.0 mg/ml)	No breakthrough for up to 240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml)	No breakthrough for up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough for up to 240 minutes
5-Fluorouracil (50.0 mg/ml)	No breakthrough for up to 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml)	No breakthrough for up to 240 minutes
Cisplatin (1.0 mg/ml)	No breakthrough for up to 240 minutes
Dacarbazine (10.0 mg/ml)	No breakthrough for up to 240 minutes
Methotrexate (25 mg/ml)	No breakthrough for up to 240 minutes
Mitomycin C (0.5 mg/ml)	No breakthrough for up to 240 minutes
Vincristine Sulfate (1.0 mg/ml)	No breakthrough for up to 240 minutes
Carmustine (BCNU) (3.3 mg/ml)	Min minutes before breakthrough =14.9
Thio-Tepa (10.0 mg/ml)	Min minutes before breakthrough =37.8
Warning Not For use with Carmustine	Warning Not For use with Thio-Tepa

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 14.9 Minutes and Thio-Tepa: 37.8 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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Traditional 510(k) Premarket Submission.
Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

510 (k) Summary – K231740

5.1 Submission Sponsor Information

US Glove Supply
300 Commerce Drive, Buffalo NY, 14218
United States
Cell Phone Number**:** 516-456-3642
E-mail**:** jacomo@glovesupply.us
Website: www.glovesupply.us
Primary Contact: Mr Jacomo Hakim
Secondary Contact: Rose Robbins
E-mail**:** Rose@glovesupply.us
Cell Phone Number:212-771-8822

5.2 Date Prepared

6/29/2023

5.3 Device Identification

Trade/Proprietary Name	Memorial^{TM} Gloves
Common Name	Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)
Classification Name	Non-Powdered Patient Examination Glove Specialty
Regulation Number	21 CFR 880.6250
Product Code	LZC, LZA, OPJ
Device Class	Class I, reserved
Classification Panel	General Hospital and Personal Use Devices

5.4 Legally marketed device(s) to which equivalence is claimed

Predicate Device:

510(k)	K172525
Trade/Proprietary Name	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
Common Name	Chemotherapy Gloves, Exam Gloves
Classification Name	Patient Examination Gloves Specialty

Regulation Number	21 CFR 880.6250
Product Code	LZC, LZA
Device Class	Class I
Classification Panel	General Hospital and Personal Use Devices

Reference device:

510(k)	K223559
Trade/Proprietary Name	Nephron Nitrile
Common Name	Nitrile Examination Gloves (Tested for Use with Chemotherapy drugs)
Classification Name	Non-Powdered Patient Examination Glove Specialty
Regulation Number	21 CFR 880.6250
Product Code	LZC, LZA, OPJ
Device Class	Class I, reserved
Classification Panel	General Hospital and Personal Use Devices

5.5 Device Description

US Glove Supply's Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) are Blue, Polymer coated, Nonsterile, Powder Free, Ambidextrous Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs. These are made up of 100% synthetic Nitrile Butadiene Latex. Its surface finish is finger textured with beaded cuff.
The device is designed and tested as per its device specific guidance; "Medical Glove Guidance Manual".

Figure 5.1: US Glove Supply's Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

Over the counter use: Yes

Single use disposable device: Yes

Sterile: No

User Profile/Population: Adults

Use Environment:

- Examination and Medical (Hospitals, Dental Clinics, Chemotherapy Centers, Home-care Centers)

5.6 Indications for Use

These Powder Free, Nitrile Examination Gloves are a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Tested Chemotherapy Drug and Concentration	**Minimum Breakthrough Detection Time**
Carmustine (BCNU) 3.3 mg/ml	Min minutes before breakthrough =14.9
Cyclophosphamide 20.0 mg/ml	No breakthrough for up to 240 minutes
Cisplatin (1.0 mg/ml)	No breakthrough for up to 240 minutes
Dacarbazine 10.0 mg/ml	No breakthrough for up to 240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml	No breakthrough for up to 240 minutes
Etoposide 20.0 mg/ml	No breakthrough for up to 240 minutes
Fluorouracil 50.0 mg/ml	No breakthrough for up to 240 minutes
Methotrexate 25 mg/ml	No breakthrough for up to 240 minutes
Mitomycin C 0.5 mg/ml	No breakthrough for up to 240 minutes
Paclitaxel (Taxol) 6.0 mg/ml	No breakthrough for up to 240 minutes
Thio-Tepa 10.0 mg/ml	Min minutes before breakthrough =37.8
Vincristine Sulfate 1.0 mg/ml	No breakthrough for up to 240 minutes

*Please note that the following drugs have low permeation times: Carmustine (BCNU): 14.9 Minutes and Thio-Tepa: 37.8 Minutes **Warning**: Not for use with Carmustine (BCNU) and Thio-Tepa.

5.7 Comparison of the technological characteristics with the predicate device

The comparison chart below provides evidence to facilitate the substantial equivalence determination between US Glove Supply Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) and the predicate device (K172525) & with reference device (K223559) with respect to the intended use, technological characteristics, and principles of operation.

Reference device (K223559) has been included in the 510K to support substantial equivalence with respect to the use of additionally claimed chemotherapy drugs than that of Predicate device.

Comparison parameters	STANDARDS	(Proposed Device)	(Predicate Device)	(Reference device)	Comparison
510(K)Number	--	K231740	K172525	K223559	Different
Manufacturer Name		US Glove Supply	Central Medicare SDN. BHD	Nephron Pharmaceuticals Corporation	Different
Name of device	--	Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs	Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)	Different
Product Code	--	LZC, LZA, OPJ	LZA, LZC	LZA, LZC, OPJ	Same with Predicate Device
Indication for use	--	These Powder Free, Nitrile Examination Gloves are a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Blue Non-Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05 and will be labelled with a statement of compliance and a summary of the testing results	Nephron Nitrile Powder-Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Similar; difference in terminology
Regulation Number	--	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same

Material	--	Nitrile		Nitrile		Nitrile		Same
Colour	--	Blue		Blue		Blue		Same
Size	--	Small, Medium, Large, X Large		Extra Small, Small, Medium, Large, Extra Large		M, L, XL, XXL		Similar; predicate device has additional sizes
Single use	--	Single use		Single use		Single use		Same
Sterile/non sterile	--	Non-sterile		Non-sterile		Non-sterile		Same
Rx Only or OTC	--	OTC		OTC		OTC		Same
Dimensions - Length	ASTM D6319-2019	Minimum 230		Minimum 230		Minimum 230		Same
Dimensions - Width	ASTM D6319-2019	S	80	XS	70	M	95	Same
		M	95	S	80	L	113	
				M	95	XL	121	
		L	110	L	110	XXL	129	
		XL	120	XL	120			
Physical Properties Tensile Strength	ASTM D6319-2019	Before aging: 14MPa, min		Before aging: 14MPa, min		Before aging: 14MPa, min		Same
		After aging:14MPa, min		After aging:14MPa, min		After aging:14MPa, min		
Physical Properties Ultimate Elongation	ASTM D6319-2019	Before aging: 500%, min		Before aging: 500%, min		Before aging: 500%, min		Same
		After aging: 400%, min		After aging: 400%, min		After aging: 400%, min		
Thickness (mm)	ASTM D6319-19	Cuff: 0.05 ± 0.02 Palm: 0.07 ± 0.02 Finger: 0.09 ± 0.02		Cuff: 0.06 ± 0.03 Palm: 0.08 ± 0.03 Finger: 0.10 ± 0.03		Palm: Minimum 0.05 mm Finger: Minimum 0.05 mm		Similar; meets ASTM D6319-19 requirements

Powder Free Residue	ASTM D6319-19	Max 1.38 mg/glove	Max. 0.52 mg per glove	≤ 2 mg per glove Average value = 0.3516 mg/glove (Medium)	Similar, meets the standard ASTM D6124 requirement of maximum 2.0 mg
Freedom from holes	ASTM D5151-2019	Meets with the requirement of ASTM D 5151, following ASTM D 6319 AQL 2.5/Inspection Level G-I	Meets with the requirement of ASTM D 5151, following ASTM D 6319 AQL 2.5/Inspection Level G-I	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	ASTM D6978-05 (2019)	Carmustine (3.3mg/ml) Min minutes before breakthrough =14.9	Carmustine (3.3mg/ml) Min minutes before breakthrough =12.4	Carmustine (3.3mg/ml) Min minutes before breakthrough =33.8	Similar
		Cisplatin (1.0 mg/ml) No breakthrough for up to 240minutes	Cisplatin (1.0 mg/ml) No breakthrough for up to 240minutes	Cisplatin (1.0 mg/ml) No breakthrough for up to 240minutes	Same
		Cyclophosphamide (20mg/ml) No breakthrough for up to 240minutes	Cyclophosphamide (20mg/ml) No breakthrough for up to 240minutes	Cyclophosphamide (20mg/ml) No breakthrough for up to 240minutes	Same
		Dacarbazine (10.0 mg/ml) No breakthrough for up to 240minutes	Dacarbazine (10.0 mg/ml) No breakthrough for up to 240minutes	Dacarbazine (10.0 mg/ml) No breakthrough for up to 240minutes	Same
		Doxorubicin HCI (2.0mg/ml) No breakthrough for up to 240minutes	Doxorubicin HCI (2.0mg/ml) No breakthrough for up to 240minutes	Doxorubicin HCI (2.0mg/ml) No breakthrough for up to 240minutes	Same
		Etoposide (20.0 mg/ml) No breakthrough for up to 240minutes	Etoposide (20.0 mg/ml) No breakthrough for up to 240minutes	Etoposide (20.0 mg/ml) No breakthrough for up to 240minutes	Same

		Fluorouracil (50.0 mg/ml) No breakthrough for up to 240minutes	Fluorouracil (50.0 mg/ml) No breakthrough for up to 240minutes	Fluorouracil (50.0 mg/ml) No breakthrough for up to 240minutes	Same
		Methotrexate (25.0 mg/ml) No breakthrough for up to 240minutes	Not tested	Methotrexate (25.0 mg/ml) No breakthrough for up to 240minutes	*Same as Reference Predicate Device
		Mitomycin C (0.5 mg/ml) No breakthrough for up to 240minutes	Not tested	Mitomycin C (0.5 mg/ml) No breakthrough for up to 240minutes	*Same as Reference Predicate Device
		Paclitaxel (6.0 mg/ml) No breakthrough for up to 240minutes	Paclitaxel (6.0 mg/ml) No breakthrough for up to 240minutes	Paclitaxel (6.0 mg/ml) No breakthrough for up to 240minutes	Same
		Thiotepa (10.0 mg/ml) Min minutes before breakthrough =37.8	Thiotepa (10.0 mg/ml) Min minutes before breakthrough =4.4	Thiotepa (10.0 mg/ml) Min minutes before breakthrough =128.1	Similar
		Vincristine Sulfate (1.0mg/ml) No breakthrough for up to 240minutes	Vincristine Sulfate (1.0mg/ml) No breakthrough for up to 240minutes	Vincristine Sulfate (1.0mg/ml) No breakthrough for up to 240minutes	Same
		Ifosfamide (50.0 mg/ml) Not tested	Ifosfamide (50.0 mg/ml) No breakthrough for up to 240minutes	Ifosfamide (50.0 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Mitoxantrone (2.0 mg/ml) Not tested	Mitoxantrone (2.0 mg/ml) No breakthrough for up to 240minutes	Mitoxantrone (2.0 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Mechlorethamine HCL (1.0 mg/ml) Not tested	Mechlorethamine HCL (1.0 mg/ml) Not tested	Mechlorethamine HCL (1.0 mg/ml) Not tested	*Will not be claimed by US Gloves

		Irinotecan (20.0 mg/ml) Not tested	Irinotecan (20.0 mg/ml) Not tested	Irinotecan (20.0 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Carboplatin (10.0 mg/ml) Not tested	Carboplatin (10.0 mg/ml) Not tested	Carboplatin (10.0 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Docetaxel (10.0 mg/ml) Not tested	Docetaxel (10.0 mg/ml) Not tested	Docetaxel (10.0 mg/ml) Not tested	*Will not be claimed by US Gloves
		Bleomycin Sulfate (15 mg/ml) Not Tested	Bleomycin Sulfate (15 mg/ml) Not tested	Bleomycin Sulfate (15 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Busulfan (6 mg/ml) Not tested	Busulfan (6 mg/ml) Not tested	Busulfan (6 mg/ml) No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Chloroquine 50mg/ml Not tested	Chloroquine 50mg/ml Not tested	Chloroquine 50mg/ml Not tested	*Will not be claimed by US Gloves
		Cyclosporin 100 mg/ml Not tested	Cyclosporin 100 mg/ml Not tested	Cyclosporin 100 mg/ml Not tested	*Will not be claimed by US Gloves
		Cytarabine HCL 100 mg/ml Not tested	Cytarabine HCL 100 mg/ml Not tested	Cytarabine HCL 100 mg/ml Not tested	*Will not be claimed by US Gloves
		Cytarabine 100 mg/ml Not tested	Cytarabine 100 mg/ml Not tested	Cytarabine 100 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Daunorubicin HCl 5 mg/ml Not tested	Daunorubicin HCl 5 mg/ml Not tested	Daunorubicin HCl 5 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves

		Docetaxel HCL 10 mg/ml Not tested	Docetaxel HCL 10 mg/ml Not tested	Docetaxel HCL 10 mg/ml Not tested	*Will not be claimed by US Gloves
		Docetaxel 10 mg/ml Not tested	Docetaxel 10 mg/ml Not tested	Docetaxel 10 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Epirubicin HCl 2 mg/ml Not tested	Epirubicin HCl 2 mg/ml Not tested	Epirubicin HCl 2 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Fludarabine 25 mg/ml Not tested	Fludarabine 25 mg/ml Not tested	Fludarabine 25 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Gemcitabine 38 mg/ml Not tested	Gemcitabine 38 mg/ml Not tested	Gemcitabine 38 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Idarubicin HCl 1 mg/ml Not tested	Idarubicin HCl 1 mg/ml Not tested	Idarubicin HCl 1 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Melphalan 5 mg/ml Not tested	Melphalan 5 mg/ml Not tested	Melphalan 5 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Rituximab 10 mg/ml Not tested	Rituximab 10 mg/ml Not tested	Rituximab 10 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
		Trisenox 1 mg/ml Not tested	Trisenox 1 mg/ml Not tested	Trisenox 1 mg/ml No breakthrough for up to 240minutes	*Will not be claimed by US Gloves
Biocompatibility	Primary skin irritation- ISO 10993 Part 23:2021	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Dermal Sensitization-	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same

	ISO 10993-10:2021				
	In vitro Cytotoxicity- ISO 10993-5: 2009	Based on the results obtained under laboratory testing conditions, test item extracts of Nitrile Examination Gloves was found to be "cytotoxic" at 100% and 50% extract and "non-cytotoxic" at 25%, 12.5% and 6.25% test item extracts to the subconfluent monolayer of L-929 mouse fibroblast cells.	----	Under the conditions of the study, the undiluted test article extract and 50% test article extract dilution did not meet the requirements of the test and the 25%, 12.5%, 6.25%, and 3.13% test article extract dilutions met the requirements of the test	Same as the Reference Predicate Device
	Acute Systemic Toxicity- ISO 10993-11: 2017	Under the conditions of this study, there was no evidence of acute systemic toxicity	---	Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity	Same as the Reference Predicate Device

*Predicate device/reference device perform additional chemotherapy drug test.

*Reference device has been included in the 510K to support substantial equivalence for the subject device with respect to the use of chemotherapy drugs Mitomycin C (0.5 mg/ml) and Methotrexate (25.0 mg/ml) which was not tested in case of the predicate device.

There are no significant differences between the products and are identical in terms of intended use, materials, design and manufacturing methods. The devices meet the ASTM standard D6319 and D6978-05 (2019).

5.8 Performance Data: Summary of non-clinical tests conducted for determination of substantial equivalence

The proposed device and its predicate devices share the same intended use, are made of the same material, are within the same minimum specifications of thickness and length by meeting ASTM D6319-19, similar permeation rates for chemotherapy drugs as per ASTM D6978-05, similar labelling, physical properties, freedom from powder, biocompatibility and water tightness.

Permeation rates for additionally claimed chemotherapy drugs Mitomycin C (0.5 mg/ml) and Methotrexate (25.0 mg/ml) which was not tested in case of the predicate device are similar to Reference device as per ASTM D6978-05. It supports substantial equivalence for the subject device with respect to the use of additionally claimed chemotherapy drugs than that of Predicate device.

Biocompatibility studies were performed on the proposed device. Under the conditions of the study, the proposed device is not a sensitizer, or an irritant.
The above test results demonstrated that the proposed device complies with the following standards: ASTM D6319-19

The results of the performance testing demonstrate fulfilment of requirements as per device specific guidance_ “Medical Glove Guidance Manual" as well as substantial equivalence with predicate. The minor differences in the product does not affect the products safety and efficacy.

Table 5.2. Non-Clinical Performance Tests

Testing/Standards	Purpose of the Test	Acceptance Criteria	Result
ASTM D-3767 Dimensions (Length, Width & thickness)	To determine the length, width and thickness of the gloves	US Glove Supply’s Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) should meet the requirements of ASTM D6319.	Pass. Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) meets the requirements of ASTM D6319
ASTM D-412/D-573 Tensile Strength & Elongation	To determine the Tensile strength and elongation in gloves before aging and after aging	*Before aging* Tensile Strength: 14MPa, min Ultimate Elongation: 500%min *After aging* Tensile Strength: 14MPa, min	Pass. Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) meets the requirements of ASTM D6319.

		Ultimate Elongation: 400%min	
ASTM D-5151 Leakage/Detection of Holes	Testing for freedom from holes as per ASTM D-5151.	The gloves should be free of holes	Pass. Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) meets the requirements of ASTM D6319
ASTM D6124 Powder Content	To Determine the powder residue using Test Method D6124.	2.0 mg Maximum	Pass. Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) meets the requirements of ASTM D6319
Permeation Testing per ASTM D6978-05 (2019)	To determine the Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Should meet the requirements as per ASTM D 6978-05	Pass. Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) meets the requirements of ASTM D-6978-05.

BIOCOMPATIBILTIY DATA

TEST DATA	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ISO 10993-23 First edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.	To evaluate the local dermal irritation of a test article extract following intracutaneous injection in rabbits.	Under the condition of study not an irritant	Under the conditions of the study, the test article met the requirements of the test
10993-10 Fourth edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.	To evaluate the test item, for the skin sensitization in Guinea pigs by maximization test.	Under the conditions of the study, not a sensitizer	Under the conditions of the study, the test article was not considered a sensitizer
ISO 10993-5 Third edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for	To determine the potential of a test article to cause cytotoxicity	Under the conditions of the study, non-cytotoxic	Based on the results obtained under laboratory testing conditions, test item extracts of Nitrile Examination Gloves

In Vitro Cytotoxicity.			was found to be "cytotoxic" at 100% and 50% extract and "non-cytotoxic" at 25%, 12.5% and 6.25% test item extracts to the subconfluent monolayer of L-929 mouse fibroblast cells.
ISO 10993-11 Third edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.	To evaluate the acute systemic toxicity of a test article, extract following injection in mice.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern.	Under the conditions of study, there was no mortality or evidence of acute systemic toxicity.

5.9 Summary of clinical tests conducted for determination of substantial equivalence or of clinical information

No clinical testing is required for this device.

5.10 Conclusions

The conclusions drawn from the non-clinical tests demonstrate that the subject device, US Glove Supply's Powder Free, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed Predicate device (K172525).