December 7, 2022

JR Engineering & Medical Technologies (M) SDN. BHD.
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. Ste 114
Aurora, Illinois 60504

Re: K221626
Trade/Device Name: Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate
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: November 10, 2022
Received: November 14, 2022

Dear Manoj Zacharias:

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

Indications for Use

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

510(k) Number *(if known)*
K221626

Device Name

Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate

Indications for Use *(Describe)*

Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Additionally, the gloves were tested for use with chemotherapy drugs and Fentanyl Citrate in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	Minimum Breakthrough Detection Time
Bendamustine (5 mg/ml)	>240 Minutes
Bleomycin (15 mg/ml)	>240 Minutes
Busulfan (6 mg/ml)	>240 Minutes
Carfilzomib (2 mg/ml)	>240 Minutes
Cetuximab (2 mg/ml)	>240 Minutes
Cladribine (1 mg/ml)	>240 Minutes
Cytarabine (100 mg/ml)	>240 Minutes
Daunorubicin HCl (5 mg/ml)	>240 Minutes
Decitabine (5 mg/ml)	>240 Minutes
Docetaxel (10 mg/ml)	>240 Minutes
Epirubicin HCl (2 mg/ml)	>240 Minutes
Fludarabine (25 mg/ml)	>240 Minutes
Fulvestrant (50 mg/ml)	>240 Minutes
Gemcitabine (38 mg/ml)	>240 Minutes
Idarubicin HCl (1 mg/ml)	>240 Minutes
Irinotecan (20 mg/ml)	>240 Minutes
Mechlorethamine (1 mg/ml)	>240 Minutes
Melphalan (5 mg/ml)	>240 Minutes
Oxaliplatin (5 mg/ml)	>240 Minutes
Paraplatin (10 mg/ml)	>240 Minutes
Pemetrexed (25 mg/ml)	>240 Minutes
Raltitrexed (0.5 mg/ml)	>240 Minutes
Rituximab (10 mg/ml)	>240 Minutes
Topotecan (1 mg/ml)	>240 Minutes
Triclosan (2 mg/ml)	>240 Minutes
Trisenox (1 mg/ml)	>240 Minutes
Velcade (Bortezomib) (1 mg/ml)	>240 Minutes
Vidaza (Azacytidine) (25 mg/ml)	>240 Minutes
Vinblastine (1 mg/ml)	>240 Minutes
Vinorelbine (10 mg/ml)	>240 Minutes
Carmustine (BCNU) (3.3 mg/ml)	35.0 Minutes
Carboplatin (10 mg/ml)	>240 Minutes

Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	64.9 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes

The following hazardous drugs (opioid) and concentration had no breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (100 mcg/2ml)

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 35.0 Minutes
Thiotepa (10 mg/ml) 64.9 Minutes

Warning: Do not use with Carmustine or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
K221626
As required by: 21CFR§807.92(c)

A. APPLICANTINFORMATION

510(K) Owner's Name	JR Engineering & Medical Technologies (M) Sdn. Bhd.
Address	Lot 8 &10, Jalan Zurah 3 & Lot 1&3, Jalan Zurah 3A/1, Pusat Perindustrian 2, 44200 Rasa, Hulu Selangor, Selangor Darul Ehsan, Malaysia.
Phone	+603-60572081
Fax	+603-60572181
E-mail	ganeshjrmt@gmail.com
Contact Person	Mr. Ganesan Subramaniam
Designation	Managing Director
Contact Number	+6012 224 6677
Contact Email	ganeshjrmt@gmail.com
Date Submitted	10th November 2022

B. DEVICE IDENTIFICATION

Name of the device	Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate
Product proprietary or trade name	**JR MEDIC**
Common or usual name	Exam Gloves
Classification name	Patient Examination Gloves, Specialty & Fentanyl and other opioid protection glove
Device Classification	Class-1
Product Code	LZA, LZC, QDO, OPJ
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Halyard Lavender Nitrile, Powder-free Exam Gloves Tested for use with Chemotherapy Drugs and Fentanyl Citrate
510(K) Number	K202622
Regulatory Class	1
Product code	LZC, QDO

D. DESCRIPTION OF THEDEVICE:

The subject device in 510(K) notification is a blue nitrile examination gloves powder free tested for use with Chemotherapy drugs and Fentanyl Citrate.

The subject device is a patient examination glove made from acrylonitrile-butadiene copolymer dispersion, blue color, powder free and non sterile (as per 21CFR 880.6250, class I). The device is

available in Small, Medium, Large and Extra Large sizes.

The subject device meets all the current specifications listed under the ASTM Specification D 6319 -2019, Standard Specification for Nitrile Examination Gloves for Medical Application. This device also complies with requirements for standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs as per ASTM D6978- 05(2019)

E. INTENDED USE OF THE DEVICE/INDICATIONS FOR USE:

Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs and Fentanyl Citrate in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	**Minimum Breakthrough Detection Time (Minutes)**
Bendamustine (5 mg/ml)	>240 Minutes
Bleomycin (15 mg/ml)	>240 Minutes
Busulfan (6 mg/ml)	>240 Minutes
Carfilzomib (2 mg/ml)	>240 Minutes
Cetuximab (2 mg/ml)	>240 Minutes
Cladribine (1 mg/ml)	>240 Minutes
Cytarabine (100 mg/ml)	>240 Minutes
Daunorubicin HCl (5 mg/ml)	>240 Minutes
Decitabine (5 mg/ml)	>240 Minutes
Docetaxel (10 mg/ml)	>240 Minutes
Epirubicin HCl (2 mg/ml)	>240 Minutes
Fludarabine (25 mg/ml)	>240 Minutes
Fulvestrant (50 mg/ml)	>240 Minutes
Gemcitabine (38 mg/ml)	>240 Minutes
Idarubicin HCl (1 mg/ml)	>240 Minutes
Irinotecan (20 mg/ml)	>240 Minutes
Mechlorethamine (1 mg/ml)	>240 Minutes
Melphalan (5 mg/ml)	>240 Minutes
Oxaliplatin (5 mg/ml)	>240 Minutes
Paraplatin (10 mg/ml)	>240 Minutes
Pemetrexed (25 mg/ml)	>240 Minutes
Raltitrexed (0.5 mg/ml)	>240 Minutes
Rituximab (10 mg/ml)	>240 Minutes
Topotecan (1 mg/ml)	>240 Minutes
Triclosan (2 mg/ml)	>240 Minutes
Trisenox (1 mg/ml)	>240 Minutes
Velcade (Bortezomib) (1 mg/ml)	>240 Minutes
Vidaza (Azacytidine) (25 mg/ml)	>240 Minutes

Vinblastine (1 mg/ml)	>240 Minutes
Vinorelbine (10 mg/ml)	>240 Minutes
Carmustine (BCNU) (3.3 mg/ml)	35.0 Minutes
Carboplatin (10 mg/ml)	>240 Minutes
Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	64.9 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes

The following hazardous drugs (opioid) and concentration had no breakthrough detected up to 240 minutes:
Fentanyl Citrate Injection (100 mcg/2ml)

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 35.0 Minutes
Thiotepa (10 mg/ml) 64.9 Minutes

Warning: Do not use with Carmustine (BCNU) & Thiotepa

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE	PROPOSED DEVICE	
510(K) Number	-	**K202622**	**K221626**	
Name of device		Halyard Lavender Nitrile, Powder-free Exam Gloves Tested for use with Chemotherapy Drugs and Fentanyl Citrate	Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate	Similar
Product Code	-	LZA, LZC, QDO	LZA, LZC, QDO, OPJ	Similar
Intended use / Indications for Use		The Halyard Lavender Nitrile, Powder-free Exam Gloves Tested for use with Chemotherapy Drugs and	Jr Medic Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs and Fentanyl Citrate is a disposable device intended for medical	Similar

		Fentanyl Citrate are disposable	purpose that is worn on the examiner's	

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE K202622	PROPOSED DEVICE	
		device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The gloves were tested for use with the chemotherapy drugs and Fentanyl Citrate as per ASTM D 6978-05	hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs and Fentanyl Citrate in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.	
Regulation Number	-	21 CFR 880.6250	21 CFR 880.6250	Same
Material	-	Nitrile	Nitrile	Same
Color	-	Lavender	Blue	Different
Size	ASTM D6319-2019	Extra Small, Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	Same
Dimensions	ASTM D6319-2019	Length: 295-325 mm Width XS- 60-80mm S- 70-90mm M- 85-105mm L- 100-120mm XL- 110-130mm	Length > 230 mm Width Min 95+/- 10 mm(for medium size)	Similar

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE DEVICE K202622	PROPOSED DEVICE K221626	
Physical Properties	ASTM D6319-2019	**Before Ageing** Tensile Strength ≥ 14 Mpa Ultimate Elongation ≥ 500% **After Ageing** Tensile Strength ≥ 14 Mpa Ultimate Elongation ≥ 400%	**Before Ageing** Tensile Strength > 14 Mpa Ultimate Elongation >500% **After Ageing** Tensile Strength >14 Mpa Ultimate Elongation > 400%	Similar
Thickness	ASTM D6319-2019	Palm 0.10-0.16 mm Finger 0.10-0.19 mm	Palm >0.05 mm Finger > 0.05 mm	Similar
Powder Free Residue	ASTM D6319-2019	≤2 mg/glove	≤2 mg/glove	Similar
Watertight (1000 ml)	ASTM D5151-2019	Passes AQL-2.5	Passes AQL-1.5	Similar
Label and Labeling	FDA Label requirements	Meets FDA's requirements	Meets FDA's requirements	Same
Bio-compatibility	Primary Skin Irritation-ISO 10993-10:2010 (E)	Under the condition of study the device extracts were not found to cause a systemic response in the animal model.	Under the condition of study not an irritant	Similar
	Dermal Sensitization-ISO 10993-10:2010 (E)	No Data Available	Under the conditions of the study not a sensitizer	----
	In vitro cytotoxicity ISO10993-5 :2009(E)	No Data Available	Under the conditions of the study, cytotoxic	----
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	No Data Available	Under the conditions of the study no material-mediated pyrogenic	----
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the conditions of the study, the test article was considered non toxic.	Under the condition of study does not induce any systemic toxic concern	Similar

Chemotherapy Drugs tested with Minimum Breakthrough Detection Time as tested per ASTM D6978-05 (2019)			
Bendamustine (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Bleomycin (15 mg/ml)	>240 Minutes	>240 Minutes	Same
Busulfan (6 mg/ml)	>240 Minutes	>240 Minutes	Same
Carfilzomib (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Cetuximab (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Cladribine (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Cytarabine (100 mg/ml)	>240 Minutes	>240 Minutes	Same
Daunorubicin HCl (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Decitabine (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Docetaxel (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Epirubicin HCl (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Fludarabine (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Fulvestrant (50 mg/ml)	>240 Minutes	>240 Minutes	Same
Gemcitabine (38 mg/ml)	>240 Minutes	>240 Minutes	Same
Idarubicin HCl (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Irinotecan (20 mg/ml)	>240 Minutes	>240 Minutes	Same
Mechlorethamine (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Melphalan (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Oxaliplatin (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Paraplatin (10 mg/ml)	Not Tested	>240 Minutes	Different
Pemetrexed (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Raltitrexed (0.5 mg/ml)	>240 Minutes	>240 Minutes	Same
Rituximab (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Topotecan (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Triclosan (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Trisenox (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Velcade (Bortezomib) (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Vidaza (Azacytidine) (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Vinblastine (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Vinorelbine (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Capecitabine (26 mg/ml)	>240 Minutes	Not Tested	Different
Carboplatin (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Cisplatin (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Cyclophosphamide (20 mg/ml)	>240 Minutes	>240 Minutes	Same
Dacarbazine (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Dactinomycin (0.5 mg/ml)	>240 Minutes	Not Tested	Different
Doxorubicin HCl (5 mg/ml)	>240 Minutes	>240 Minutes	Same
Etoposide (20 mg/ml)	>240 Minutes	>240 Minutes	Same
5-Fluorouracil (50 mg/ml)	>240 Minutes	>240 Minutes	Same

Ifosfamide (50 mg/ml)	>240 Minutes	>240 Minutes	Same
Leuprolide Acetate Salt (5 mg/ml)	>240 Minutes	Not Tested	Different
Methotrexate (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitomycin C (0.5 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitoxantrone (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Paclitaxel (6 mg/ml)	>240 Minutes	>240 Minutes	Same
Temsirolimus (25 mg/ml)	>240 Minutes	Not Tested	Different
Vincristine (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Zoledronic Acid (0.8 mg/ml)	>240 Minutes	Not Tested	Different
Carmustine (3.3 mg/ml)	0.3 Minutes	35.0 Minutes	Different
Thiotepa (10 mg/ml)	30.9 Minutes	64.9 Minutes	Different
Hazardous Drugs (opioid) tested with Minimum Breakthrough Detection Time as tested per ASTM D6978-05 (2019)			
Fentanyl Citrate (100 mg/ml)	>240 Minutes	>240 Minutes	Same

There are no significant differences between the proposed device and the predicate device and are identical in terms of intended use, materials, design, manufacturing methods & resistance of medical gloves to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978- 05(2019).

G. NON-CLINICAL TESTING SUMMARY PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 220 mm for Size Small & Min 230 mm for all other sizes	Small:- 404 mm Medium:- 405 mm Large:- 405 mm X-Large:- 406 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Small:- 80+/-10 mm Medium:- 95+/-10mm Large:- 110+/-10 mm X-Large:-120+/10 mm	Small:- 84 mm Medium:- 94 mm Large:- 105 mm X-Large:- 115 mm		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Size Small Medium Large X-Large	Palm 0.19mm 0.19mm 0.19mm 0.19mm	Finger 0.21mm 0.21mm 0.21mm 0.21mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** Small Medium Large X-Large	**Before ageing** 22.77Mpa 24.46Mpa 24.51Mpa 24.59Mpa	**After ageing** 20.50Mpa 21.81Mpa 21.95Mpa 22.05Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% Min for all sizes **After Ageing** Ultimate Elongation 400% Min for all sizes	**Size** Small Medium Large X-Large	**Before ageing** 885% 888% 891% 892%	**After ageing** 868% 870% 872% 875%

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-2019 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 1.5	
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	**Size** Small Medium Large X-Large	**Residual Powder Content** 0.16 mg/glove 0.16 mg/glove 0.16 mg/glove 0.16mg/glove

PERMEATION TEST RESULT AS PER ASTM D6978

Test Chemotherapy Drugs	***Minimum Breakthrough Detection Time (Minutes)***	**Avg. Steady State Perm. Rate (µg/cm^2/Minute)**	**Other Observations**
Bendamustine (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Bleomycin (15 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Busulfan (6 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Carfilzomib (2 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Cetuximab (2 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Cladribine (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Cytarabine (100 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Daunorubicin HCl (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Decitabine (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Docetaxel (10 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Epirubicin HCl (2 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Fludarabine (25 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Fulvestrant (50 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Gemcitabine (38 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Idarubicin HCl (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Irinotecan (20 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Mechlorethamine (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Melphalan (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Oxaliplatin (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Paraplatin (10 mg/ml)	Not Tested	NA	Slight swelling & no degradation
Pemetrexed (25 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Raltitrexed (0.5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Rituximab (10 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Topotecan (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Triclosan (2 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Trisenox (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Velcade (Bortezomib) (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Vidaza (Azacytidine) (25 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Vinblastine (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Vinorelbine (10 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Carboplatin (10 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Cisplatin (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Cyclophosphamide (20 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Dacarbazine (10 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Doxorubicin HCl (5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Etoposide (20 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
5-Fluorouracil (50 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Ifosfamide (50 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation

Test Chemotherapy Drugs	*Minimum Breakthrough Detection Time (Minutes)*	Avg. Steady State Perm. Rate (µg/cm^2/Minute)	Other Observations
Methotrexate (25 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Mitomycin C (0.5 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Mitoxantrone (2 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Paclitaxel (6 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Vincristine (1 mg/ml)	>240 Minutes	NA	Slight swelling & no degradation
Carmustine (3.3 mg/ml)	35.0 Minutes	NA	Slight swelling & no degradation
Thiotepa (10 mg/ml)	64.9 Minutes	NA	Slight swelling & no degradation

H. NON- CLINICAL TESTING BIO-COMPATABILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation.	To determine the potential of the material under test to produce dermal irritation in Rabbits	Non irritant	Under the condition of study not an irritant
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done Skin sensitization.	To determine the skin sensitization potential of the material both in terms of induction and elicitation in Guinea Pig.	Non sensitizer	Under the conditions of the study not a sensitizer
ISO 10993-5:2009 biological evaluation of medical devices - part 5, tests for in vitro cytotoxicity.	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method.	Non cytotoxic	Under the conditions of the study cytotoxic.
ISO 10993-11:2017 biological evaluation of medical devices - part 11, tests for systemic toxicity.	To determine the acute systemic toxicity potential of the test item extracts (both inside and outer surfaces) in Swiss Albino mice.	Not pose systemic toxicity concern	Under the conditions of study the device extracts do not pose acute systemic toxicity concern
Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	To determine the pyrogenic potential of the test item extract following intravenous injection in New Zealand white Rabbits.	Not pose material mediated pyrogenicity response	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.

I. Clinical Testing Summary

No clinical information is included in this submission

J. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.