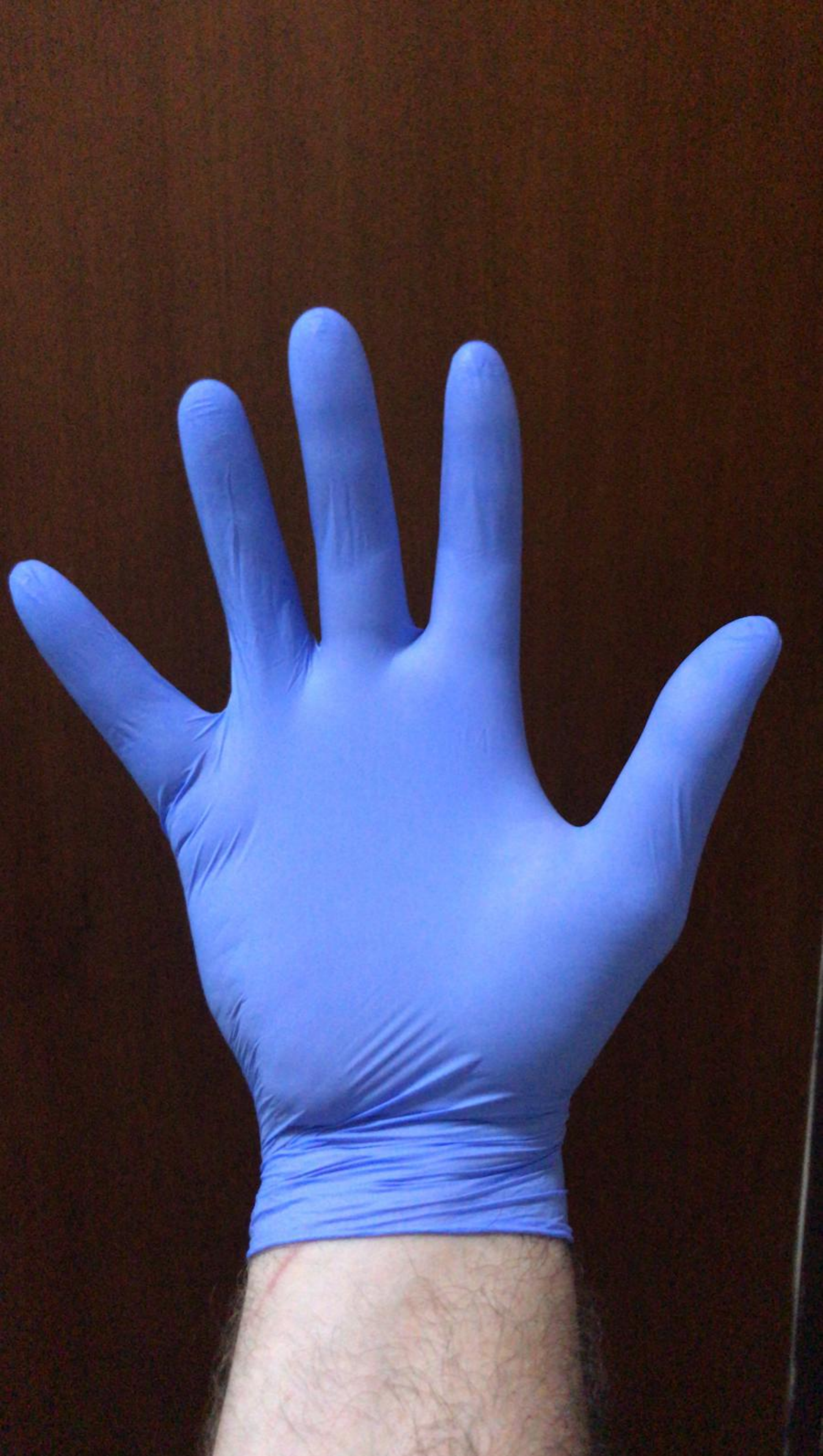

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2009

Comfort Rubber Gloves IND. SDN. BHD.
Mr. Tan K. Beng
Managing Director
Lot 821, Jalan Matang, 34750 Matang
Taiping, Perak
MALAYSIA

Re: K083624
Trade/Device Name: Powder Free Nitrite (Blue and White) Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 19, 2009
Received: January 26, 2009

Dear Mr. Beng.

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant : Comfort Rubber Gloves Ind. Sdn. Bhd.

510(k) Number (if known): K083624

Device Name: POWDER FREE NITRILE (BLUE AND WHITE) EXAMINATION GLOVES.

Indications for Use:

A powder-free patient examination glove is a disposable device made of synthetic material that is intended for medical purposes to be worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda A Murphy MD

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K083624

June 27, 2019

Comfort Rubber Gloves Industries Sdn. Bhd.
Chan Men
QA & QMS Manager
Lot 821, Jalan Matang
Matang, 34750 My

Re: K190080
Trade/Device Name: Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: March 28, 2019
Received: April 01, 2019

Dear Chan Men:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190080

Device Name
Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black)

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black) is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested for use chemotherapy drugs. Tested drugs are as follows:

	Average Breakthrough Detection Time (minutes)
Cisplatin 1.0 mg/ml	≥ 240
Cyclophosphamide (Cytoxan) 20 mg/ml	≥ 240
Dacarbazine (DTIC) 10.0 mg/ml	≥ 240
Doxorubicin Hydrochloride 2.0 mg/ml	≥ 240
Etoposide (Toposar) 20.0 mg/ml	≥ 240
Fluorouracil 50.0 mg/ml	≥ 240
Paclitaxel (Taxol) 6.0 mg/ml	≥ 240

Please note that the following drugs have extremely low permeation time for
*Carmustine (BCNU) 3.3mg.ml – 54.1 (mins)
*Thiotepa 10.0 mg/ml - 16.0 (mins)

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.

510(k) SUMMARY K190080

POWDER FREE NITRILE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM (BLACK)

1.0 Submitter:

Name : Comfort Rubber Gloves Industries Sdn. Bhd.
Address : Lot 821, Jalan Matang,
34750 Matang, Perak, Malaysia.
Malaysia.
Phone No. : 605-847 2777
Fax No. : 605-847 9108
Contact Person: Chan Yew Men (Mr.)

Date of Preparation: June 27, 2019

2.0 Name of the Device

Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black)

Common Name: Patient Examination Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250 product code LZA)
Patient Examination Gloves Specialty (21 CFR 880.6250 product code LZC

510(K) Number: K190080

3.0 Predicate Device

Device Name: Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green)
Company: Comfort Rubber Gloves Industries Sdn. Bhd. 510(K)

No.: K180476

4.0 Description of the Device:

Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black) meets all the requirements of ASTM D6319 - 10(2015) Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Indication for Use of the Device

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black) are a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested for use with chemotherapy drugs.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black) are summarized with the following technological characteristics compared to ASTM D6319 - 10(2015) Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards as shown in Table 1.

Chemotherapy claim is similar to Predicate, which has a gloves thickness comply with the ASTM Standards.

Table 1

CHARACTERISTICS	**STANDARDS**	**PREDICATE DEVICE K180476**	**SUBJECT DEVICE K190080**	**COMPARISON**
Manufacturer(s)		Comfort Rubber Gloves Industries Sdn. Bhd	Comfort Rubber Gloves Industries Sdn. Bhd	Same
Device Name		Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green)	Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black)	Similar
Dimension	ASTM 6319-10 (2015)	Length-Min 240mm Thickness palm and finger-Min 0.05mm	Length-Min 230mm Thickness palm and finger-Min 0.05mm	Similar
Physical Properties	ASTM 6319-10 (2015)	Min - 20.23 MPa Min - 445 %	Min – 22.31 MPa Min – 579%	Similar
Thickness – Finger - Palm	ASTM 6319-10 (2015)	0.09 mm- 0.10 mm 0.12mm – 0.14 mm	0.09 mm- 0.10 mm 0.11 mm – 0.13 mm	Similar
Powder Content	ASTM 6124-06 (2011) (≤ 2 mg/glove)	**Max - 2 mg/gloves** 0.20 mg/glove	**Max - 2 mg/gloves** 0.60 mg/glove	Same
Chemotherapy Drug Permeation Test	ASTM D6978-05	Below	Below	Similar
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine (BCNU)	3.3 mg/ml	23.4	54.1	
Cisplatin	1.0 mg/ml	>240	>240	
Cyclophosphamide (Cytoxan)	20 mg/ml	>240	>240	
Dacarbazine (DTIC)	10.0 mg/ml	>240	>240	
Doxorubicin Hydrochloride	2.0 mg/ml	>240	>240	
Etoposide (Toposar)	20.0 mg/ml	>240	>240	
Fluorouracil	50.0 mg/ml	>240	>240	
Paclitaxel (Taxol)	6.0 mg/ml	>240	>240	
*Thiotepa	10.0 mg/ml	16.2	16.0	
Warning Statement		* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 23.4 minutes and Thiotepa: 16.0 minutes.	* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 54.1 minutes and Thiotepa: 16.0 minutes.	

CHARACTERISTICS	STANDARDS	PREDICATE DEVICE K180476	SUBJECT DEVICE K190080	COMPARISON
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device extracts are not irritating to the animal model.	Under the conditions of the study, the subject device extracts are not irritating to the animal model.	Same
	ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device extracts are not sensitizing to the animal model.	Under the conditions of the study, the subject device extracts are not sensitizing to the animal model.	Same
	Cytotoxicity ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (score of 2) with the neat extract (100%).	Under the conditions of the study, the subject device extract exhibits mild cytotoxicity reactivity result (score of 2) with the neat extract (100%).	Same
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes	Passes	Same
Indication for Use		The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green) is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested chemotherapy drugs are as follows: Average Breakthrough Detection Time (minutes Cisplatin, 1.0 mg/ml - ≥ 240 Cyclophosphamide Cytoxan), 20.0 mg/ml - ≥ 240 Dacarbazine (DTIC), 10.0 mg/ml - ≥ 240 Doxorubicin Hydrochloride, 2.0 mg/ml - ≥ 240 Etoposide (Toposar), 20.0 mg/ml - ≥ 240 Fluorouracil, 50.0 mg/ml - ≥ 240 Paclitaxel (Taxol), 6.0 mg/ml - ≥ 240 Please note that the	The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black) is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested chemotherapy drugs are as follows: Average Breakthrough Detection Time (minutes) Cisplatin, 1.0 mg/ml - ≥ 240 Cyclophosphamide (Cytoxan), 20.0 mg/ml - ≥ 240 Dacarbazine (DTIC), 10.0 mg/ml - ≥ 240 Doxorubicin Hydrochloride, 2.0 mg/ml - ≥ 240 Etoposide (Toposar), 20.0 mg/ml - ≥ 240 Fluorouracil, 50.0 mg/ml - ≥ 240 Paclitaxel (Taxol), 6.0 mg/ml - ≥ 240 Please note that the	Same

		following drugs have extremely low permeation time for: Carmustine (BCNU) 3.3mg/ml - 23.4 (mins) Thiotepa 10.0 mg/ml - 16.2 (mins	following drugs have extremely low permeation time for: Carmustine (BCNU) 3.3mg/ml - 54.1 (mins) Thiotepa 10.0 mg/ml – 16.0 (mins	
Material	ASTM D6319 - 10(2015)	Nitrile	Nitrile	Same
Color		Green	Black	Different
Size	Medical Glove Guidance Manual Labeling	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Single Use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use	Same

7.0 Summary of Non-Clinical Performance Data

Non-clinical tests were conducted to demonstrate that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

- ASTM D412-2016 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven
- ASTM D3767-03 Standard Practice for Rubber Measurement of Dimensions
- ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-2006 (Reapproved 2001) Standard Tested Method for Residual Powder on Medical Gloves
- ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6978-2005(Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes
- ISO 10993-5 Biological evaluation of medical devices-Part5 Tests for in vivo cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices-Part 10 Test for irritation and delayed-type hypersensitivity

8.0 Clinical Performance Data

Clinical data is not needed.

9.0 Conclusion

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

1.0 DESIGN AND FEATURE

1.1 Material : *Nitrile synthetic latex*

1.2 Features : *Non-sterile, finger textured, beaded and ambidextrous*

1.3 Color : *Blue(OCF35NBBL), Black(OCF35NBBK), Dark blue(OCF35NBDB), Sky blue(OCF35NBSB), Magenta(OCF35NBMG), Violet blue(OCF35NBVB), White(OCF35NBWH).*

1.4 Size range : *X-Small, Small, Medium, Large, X-Large, XX-Large*

1.5 Length : *As per item 2.1.1*

1.6 Finishing : *Chlorinated*

2.0 PROPERTIES AND REQUIREMENTS

2.1 Dimensions

2.1.1 Palm width and Length

Glove size	Palm width (mm)	Length (mm)	Inspection Level / AQL
XS	*75 ± 5mm*	*Min 240*	*S2/AQL 4.0*
S	*85 ± 5mm*		
M	*95 ± 5mm*		
L	*105 ± 5mm*		
XL	*115 ± 5mm*		
XXL	*>120mm*		

2.1.2 Thickness

Location of thickness measurements	Single wall (mm)	Inspection Level / AQL
Finger (13mm from Tip)	*0.10 ± 0.02mm*	*S2/AQL 4.0*
Palm (center of the palm)	*0.07 ± 0.02mm*	
Cuff (25mm from the bead)	*0.06 ± 0.01mm*	

2.1.3 Weight

Glove size	Weight (g)
XS	*2.9 ± 0.2*
S	*3.2 ± 0.2*
M	*3.5 ± 0.2*
L	*3.8 ± 0.2*

XL	*4.1 ± 0.2*
XXL	*4.4 ± 0.2*

2.2 Pin holes

Characteristics	Inspection Level / AQL
Freedom from holes	*GI/AQL 1.5*

2.3 Major Visual

Characteristics	Inspection Level / AQL
Major visual defects	*GI/AQL 2.5*

2.4 Physical properties

Characteristics	Reference Standard	Before Aging	After Aging	Inspection Level / AQL
Force At Break (N)	*EN 455, part 2*	*Min 6*	*Min 6*	*S2/AQL 4.0*
Tensile Strength (Mpa)	*ASTM D 6319*	*Min 14*	*Min 14*	
Ultimate Elongation (%)	*ASTM D 6319*	*Min 500*	*Min 400*	

2.5 Powder content

Characteristics	Reference Standard	mg/glove
Powder content	*ASTM D 6124*	*Max 2*

2.6 Protein content

Characteristics	Reference Standard	ug/dm^2
Protein content	*ASTM D 5712*	*N/A*

3.0 PACKAGING

3.1 Packaging : *Each dispenser box contain 100 gloves and 10 dispensers in a shipping case.*

4.0 PACKING LOT IDENTIFICATION

4.1 Packing lot number : *YMMPPXXX*

Y = *Year of packing*
MM = *Month of packing*
PP = *Product type (AA-NR powdered, BB-NR powder free, CC-NBR powdered, DD-NBR powder free)*

XXX = Sequential number shipped out for a month by size

4.2 *Applicable for internal use only unless requested by customer.*

5.0 CERTIFICATE OF RELEASE

5.1 Certificate of release : *A Certificate of Release is available upon request to ensure all gloves shipped conform to specified specification.*

6.0 PRODUCT SHELF LIFE

6.1 Shelf Life : *3 Years*