DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 28, 2017

Comfort Rubber Gloves Industries Sdn Bhd
Chan Men
QA & QMS Manager
Lot 821, Jalan Matang
Matang, Perak 84750 MY

Re: K162405
Trade/Device Name: Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs Labeling Claim (White)
Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs Labeling Claim (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: February 17, 2017
Received: February 22, 2017

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. 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 and Part 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Division Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162405

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

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (White) 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 with 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
Carmustine (BCNU) 3.3mg/ml	24.0 (mins)
Thiotepa 10.0 mg/ml	54.9 (mins)

Please note that the following drugs have extremely low permeation time for:

Carmustine (BCNU) 3.3mg/ml - 24.0 (mins)
Thiotepa 10.0 mg/ml - 54.9 (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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162405

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

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue) 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 with 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
Carmustine (BCNU) 3.3mg/ml	18.2 (mins)
Thiotepa 10.0 mg/ml	57.3 (mins)

Please note that the following drugs have extremely low permeation time for:

Carmustine (BCNU) 3.3mg/ml - 18.2 (mins)
Thiotepa 10.0 mg/ml - 57.3 (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.

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Attachment 17

510(k) SUMMARY

POWDER FREE NITRILE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM (BLUE AND WHITE)

510(k) SUMMARY

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 : March 28, 2017

2.0 Name of the Device

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

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

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	:	K162405

3.0 Identification of The Legally Marketed Devices That equivalency is claimed:

Predicate

Device Name : Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs

Company : WRP Asia Pacific Sdn Bhd

510(K) No. : K141982

4.0 Description of the Device:

The proposed devices are Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim. The gloves are available in two colors: blue and white. The proposed devices are non-sterile. The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue and White) meet all the requirements of ASTM Specification 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 (White) 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 with 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
Carmustine (BCNU) 3.3 mg/ml	24.0 (mins)
Thiotepa 10.0 mg/ml	54.9 (mins)

Please note that the following drugs have extremely low permeation time for:

Carmustine (BCNU) 3.3 mg/ml – 24.0 (mins)
Thiotepa 10.0 mg/ml – 54.9 (mins)

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue) 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 with 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
Carmustine (BCNU) 3.3 mg/ml	18.2 (mins)
Thiotepa 10.0 mg/ml	57.3 (mins)

Please note that the following drugs have extremely low permeation time for:

Carmustine (BCNU) 3.3 mg/ml – 18.2 (mins)
Thiotepa 10.0 mg/ml – 57.3 (mins)

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue and White) 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.

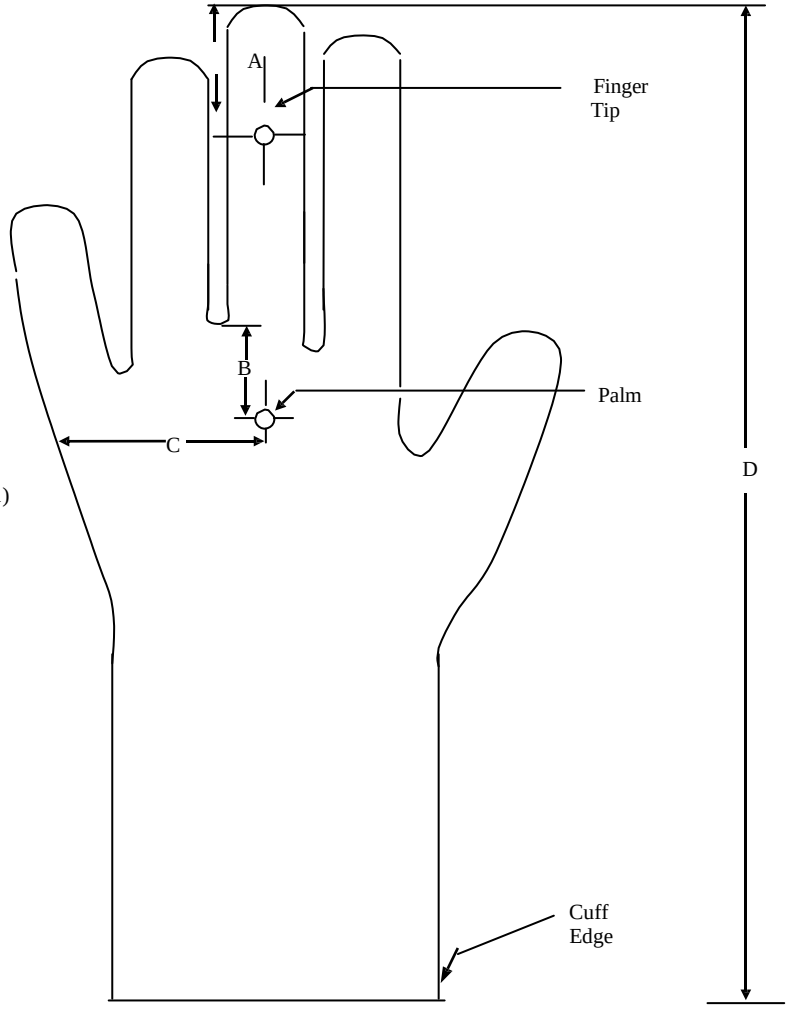
Chemotherapy claim is similar to Predicate, which has a gloves thickness comply with the ASTM Standards.

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate 1	Current
Manufacturer(s)		WRP Asia Pacific Sdn Bhd	Comfort Rubber Gloves Industries Sdn. Bhd
510(k) number		K141982	-
Length	ASTM D6319 - 10(2015)	Length-Min 240mm width - min 85 mm for medium glove	Length-Min 240mm width - min 85 mm for medium glove
Physical Properties	ASTM D6319 - 10(2015)	Meets min 14Mpa before and after aging. Meets min 500% before aging and min 400% after aging.	Meets min 14Mpa before and after aging Meets min 500% before aging and min 400% after aging.
Thickness – Finger - Palm	ASTM D6319 - 10(2015)	Meets min .05 mm for palm and finger thickness.	Meets min .05 mm for palm and finger thickness.
Powder Content	ASTM D6124 - 06(2011) (≤ 2 mg/glove)	Meets	Meets

Distance	mm
A	13 ± 3
B	33 ± 5
C	48 ± 9 (Note 1)
D	Length

Note 1 - Dimension C to locate approximate center of palm with respect to Glove size



Location of thickness and length Measurement

Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue and White)

Attachment 17

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue)			
Chemotherapy Drug Permeation Test	ASTM D6978-05		
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**	
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
Ifosfamide	50.0 mg/ml	>240	-
Mitoxantrone	2.0 mg/ml	>240	-
Vincristine Sulfate	1.0 mg/ml	>240	-
*Carmustine (BCNU)	3.3 mg/ml	15.0	18.2
*Thiotepa	10.0 mg/ml	2.0	57.3
Warning Statement		* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 15 minutes and Thiotepa : 2 minutes.	* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 18.2 minutes and Thiotepa : 57.3 minutes.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (White)			
Chemotherapy Drug Permeation Test	ASTM D6978-05		
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**	
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
Ifosfamide	50.0 mg/ml	>240	-
Mitoxantrone	2.0 mg/ml	>240	-
Vincristine Sulfate	1.0 mg/ml	>240	-
*Carmustine (BCNU)	3.3 mg/ml	15.0	24.0
*Thiotepa	10.0 mg/ml	2.0	54.9
Warning Statement		* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 15 minutes and Thiotepa : 2 minutes.	* WARNING : Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 24.0 minutes and Thiotepa : 54.9 minutes.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate	Current
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Passes Under the conditions of the study, the subject device is non-irritating	Passes Under the conditions of the study, the subject device is non-irritating
	Dermal Sensitization ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Passes Under the conditions of the study, the subject device is non-sensitization	Passes Under the conditions of the study, the subject device is non-sensitization
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes	Passes
Indication for Use		A patient examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue and White) 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.
Material	ASTM D6319 - 10(2015)	Nitrile	Nitrile
Color	-	Blue	Blue or White
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

The device and the predicate share the same indication for use, same material, same specifications for thickness and length, similar permeation rate for chemotherapy drugs, similar labeling properties, powder free, biocompatibility and water tight test. Thus, the device substantially equivalent to the predicate.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for this device.

9.0 Conclusion

Based on indication for use, technological characteristics and non-clinical performance data, the Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Blue and White) device - K162405 is substantially equivalent to the predicate device K141982.