May 15, 2018

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

Re: K180476
Trade/Device Name: Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC, LZA
Dated: February 12, 2018
Received: February 22, 2018

Dear Chan Yew 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); 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180476

Device Name

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

Indications for Use *(Describe)*

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 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 – 23.4 (mins)
*Thiotepa 10.0 mg/ml - 16.2 (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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510(k) SUMMARY

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

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: April 17, 2018

2.0 Name of the Device

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

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	:	K180476

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

Predicate

Device Name	: 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)
Company	: Comfort Rubber Gloves Industries Sdn. Bhd.
510(K) No.	: K162405

4.0 Description of the Device:

The proposed device is the Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green). The proposed device is for single use and is provided non-sterile. The device meets the requirements for dimensions, physical properties, and thickness in ASTM D6319 - 10(2015) Standard Specification for Nitrile Examination Gloves for Medical Application. The device accomplishes its intended function by creating a

physical barrier between the examiner and patient and creates a barrier for the chemotherapy drugs listed in the Indications for Use.

5.0 Indication for Use of the Device

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green) 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. 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) 3.3 mg/ml – 23.4 (mins)
*Thiotepa 10.0 mg/ml – 16.2 (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 (Green) 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.

The chemotherapy claim is similar to the Predicate, which has a gloves thickness which complies with the ASTM standard ASTM D6319 – 10(2015): Standard Specification for Nitrile Examination Gloves for Medical Application.

Comparison of technological characteristics with the predicate device

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		
		Predicate	Current	Comparison
Manufacturer(s)		Comfort Rubber Gloves Industries Sdn. Bhd	Comfort Rubber Gloves Industries Sdn. Bhd	Same
510(k) number		K162405	K180476	
Dimension	ASTM D6319 - 10(2015)	Length-Min 240mm Thickness palm and finger- Min 0.05mm	Length-Min 240mm Thickness palm and finger- Min 0.05mm	Same
Physical Properties	ASTM D6319 - 10(2015)	Meets	Meets	Same
Thickness – Finger - Palm	ASTM D6319 - 10(2015)	Meets	Meets	Same
Powder Content	ASTM D6124 - 06(2011) (≤ 2 mg/glove)	Meets	Meets	Same

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

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		
		Predicate	Current	Comparison
		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 (Green)	
Chemotherapy Drug Permeation Test	ASTM D6978-05			
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine (BCNU)	3.3 mg/ml	18.2	23.4	Similar – The chemotherapy drugs tested have similar breakthrough detection times; the drugs with low permeation times are the same.
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	57.3	16.2	
Warning Statement		* WARNING: Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 18.2 minutes and Thiotepa: 57.3 minutes.	* WARNING: Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 23.4 minutes and Thiotepa: 16.2 minutes.	

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		
		Predicate	Current	Comparison
		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 (Green)	
Chemotherapy Drug Permeation Test	ASTM D6978-05			
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine (BCNU)	3.3 mg/ml	24.0	23.4	Similar – The chemotherapy drugs tested have similar breakthrough detection times; the drugs with low permeation times are the
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	54.9	16.2	
Warning Statement		* WARNING :	* WARNING :	

	Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 24.0 minutes and Thiotepa: 54.9 minutes.	Please note that the following drugs have extremely low permeation times Carmustine (BCNU): 23.4 minutes and Thiotepa: 16.2 minutes.	same.

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		
		Predicate	Current	Comparison
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	Same
Biocompatibility: 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	Same
Biocompatibility: Cytotoxicity and acute systemic toxicity	ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for *in vitro* cytotoxicity ISO 10993-5:2017 Biological evaluation of medical devices -- Part 5: Tests for systemic toxicity	N/A	Passes Certificate of Analysis for the color imparting compound indicates that the compound meets technical specifications, is non-cytotoxic, and is not systemically toxic.	Different
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 (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	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	Similar

		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 following drugs have extremely low permeation time for: Carmustine (BCNU) 3.3mg/ml - 18.2 (mins) Thiotepa 10.0 mg/ml - 57.3 (mins) 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	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 following drugs have extremely low permeation time for: Carmustine (BCNU) 3.3mg/ml - 23.4 (mins) Thiotepa 10.0 mg/ml - 16.2 (mins)	

		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 following drugs have extremely low permeation time for: Carmustine (BCNU) 3.3mg/ml - 24.0 (mins) Thiotepa 10.0 mg/ml - 54.9 (mins)		

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		
		Predicate	Current	Comparison
Material	ASTM D6319 - 10(2015)	Nitrile	Nitrile	Same
Color	-	Blue or White	Green	Different
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large	Extra Small Small Medium Large	Same

		Extra Large	Extra Large	
Single Use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use	Same

7.0 Summary of Non-Clinical Performance Data

The device and the predicate share the same indication for use, same base polymeric material, same specifications for thickness and length, similar permeation rate for chemotherapy drugs, similar labeling properties, biocompatibility per ISO 10993-1, water tight test results, and are powder free.

8.0 Summary of Clinical Performance Data

Clinical data is not needed for the intended use for this device.

9.0 Conclusion

Based on the Indication for Use, technological characteristics, and non-clinical performance data, the Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Green) (K180476) is as safe, as effective, and performs as well as the legally marketed predicate device (K162405).