DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 20, 2017

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

Re: K171541
Trade/Device Name: Powder Free Nitrile Examination Gloves (Orange)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: August 29, 2017
Received: September 1, 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); 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), please contact the Division of Industry and Consumer Education (DICE) 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 (DICE) 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,

Tara A. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171541

Device Name

Powder Free Nitrile Examination Gloves (Orange)

Indications for Use *(Describe)*

The Powder Free Nitrile Examination Gloves (Orange) 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.

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

POWDER FREE NITRILE EXAMINATION GLOVES (ORANGE)

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 : September 8, 2017

2.0 Name of the Device

Powder Free Nitrile Examination Gloves (Orange)

Common Name	:	Patient Examination Gloves
Regulation Name	:	Patient Examination Gloves (21 CFR 880.6250 product code LZA)
Device Class	:	Class I
510(K) Number	:	K171541

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

Predicate

Device Name : Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile

Company : WRP Rubber Products Sdn. Bhd.

510(K) No. : K140418

4.0 Description of the Device:

The proposed devices are Powder Free Nitrile Examination Gloves (Orange).
The gloves are available in orange color. The proposed devices are non-sterile. The Powder Free Nitrile Examination Gloves (Orange) meet all the requirements of ASTM Specification D6319-10 (2015) – Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Intended Use of the Device

The Powder Free Nitrile Examination Gloves (Orange) 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.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves (Orange) 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 and Figure 1 on Location of thickness and length measurement.

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		Predicate	Current	
Manufacturer(s)		WRP Rubber Products Sdn Bhd	Comfort Rubber Gloves Industries Sdn. Bhd	N/A
510(k) number		K140418	K171541	N/A
Length	ASTM D6319 - 10(2015)	Length-Min 230mm width - min 95 ± 10 mm	Length-Min 240mm width - min 85 mm for medium glove	Same
Physical Properties	ASTM D6319 - 10(2015)	Meets Before Aging Tensile Strength min 14 MPa Ultimate Elongation Min 500% After Aging Tensile Strength min 14 MPa Ultimate Elongation Min 400%	Meets Before Aging Tensile Strength Min 14 MPa Ultimate Elongation Min 500% After Aging Tensile Strength min 14 MPa Ultimate Elongation Min 400%	Same
Thickness – Finger - Palm	ASTM D6319 - 10(2015)	Meets Palm - Min 0.05mm Finger - Min 0.05mm	Meets Palm - Min 0.05mm Finger - Min 0.05mm	Same
Powder Content	ASTM D6124 - 06(2011) (≤ 2 mg/glove)	Meets ≤ 2 mg/glove	Meets ≤ 2 mg/glove	Same
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin	Under the conditions of the study, not an irritant.	Passes Under the conditions of the study, the subject device is non-irritating	Same

	sensitization			

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		substantially equivalent to predicate
		Predicate	Current	
	Dermal Sensitization ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, not a sensitizer.	Passes Under the conditions of the study, the subject device is non-sensitizing	Same
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes AQL 2.5	Passes AQL 2.5	Same
Intended Use	-	A patient examination glove 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 (Orange) 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.	Same
Material	ASTM D6319 - 10(2015)	Nitrile	Nitrile	Similiar
Color	-	Blue	Orange	-
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large Extra Large	Extra Small - 75mm±5mm Small - 85mm±5mm Medium - 95mm±5mm Large - 105mm±5mm Extra Large -115mm±5mm Double Extra Large > 120mm Length-Min 240mm	Same
Single Use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use	Same

7.0 Non-Clinical Performance Data Conclusion:

The subject device and the predicate non-clinical testing results demonstrate that the devices are similar or the same for the following non-clinical testing endpoints: physical properties (same specifications for thickness and length), powder content, biocompatibility, and water tight test.

8.0 Clinical Performance Data Conclusion:

NA

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the Powder Free Nitrile Examination Gloves (Orange) device is substantially equivalent to the predicate device K140418.