August 24, 2022

Comfort Rubber Gloves Industries Sdn. Bhd.
Ng Kok Howe
QA Manager
Lot 821, Jalan Matang
Matang, 34750
Malaysia

Re: K192954
Trade/Device Name: Blue Colored, Power Free Nitrile Examination Gloves 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, QDO

Dear Ng Kok Howe:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 19, 2020. Specifically, FDA is updating this SE Letter for a typographical error contained in the Indications for Use and 510(k) Summary, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Bifeng Qian, Office of Surgical and Infection Control Devices, at: (301) 796-2261 or bifeng.qian@fda.hhs.gov.

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

June 19, 2020

Comfort Rubber Gloves Industries Sdn. Bhd.
Ng Kok Howe
QA Manager
Lot 821, Jalan Matang
Matang, 34750 My

Re: K192954
Trade/Device Name: Blue Colored, Power Free Nitrile Examination Gloves 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, QDO,
Dated: November 29, 2019
Received: May 11, 2020

Dear Ng Kok Howe:

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,

Elizabeth F. Claverie -S

FDA

CAPT Elizabeth Claverie, M.S.
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

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)*
K192954

Device Name

Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*

The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam 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. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:	Average Breakthrough Detection Time (minutes)
Cisplatin 1.0 mg/ml	≥ 240
Cyclophosphamide (Cytoxan) 20 mg/ml	≥ 240
Dacarbazine (DTIC) l 0.0 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
Thiotepa (THT) -10.0 mg/ml	57.3

Tested Fentanyl Citrate is as follows:	Average Breakthrough Detection Time
Fentanyl Citrate Injection 100.0 mcg/2ml	(minutes) ≥ 240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 18.2 minutes and Thiotepa: 57.3
minutes. Warning: Do not use with Carmustine.

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 - K192954

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	:	Ng Kok Howe (Mr.)

Date of Preparation : June 10, 2020

2.0 Name of the Device

Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Common Name	:	Patient Examination Gloves
Classification Name	:	Patient Examination Gloves (21 CFR 880.6250) Patient Examination Gloves Specialty (21 CFR 880.6250
510(K) Number	:	K192954
Device Class	:	I
Product code	:	LZA, LZC, QDO

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

Predicate

Device Name : Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Company : Kossan International Sdn. Bhd.

510(K) No. : K183287

4.0 Description of the Device:

Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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 Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy 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
Carmustine (BCNU) -3.3 mg/ml	18.2
Thiotepa (THT) -10.0 mg/ml	57.3

Tested Fentanyl Citrate is as follows:

	Average Breakthrough Detection Time (minutes)
Fentanyl Citrate Injection 100.0 mcg/2ml	≥ 240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 18.2 minutes and Thiotepa: 57.3 minutes. Warning: Do not use with Carmustine.

6.0 Summary of the Technological Characteristics of the Device:

The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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

Technological Characteristic Comparison Table

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
Manufacturer(s)		Kossan International Sdn. Bhd.	Comfort Rubber Gloves Industries Sdn. Bhd	Different
510(k) number		K183287	K192954	
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	Similar
Physical Properties	ASTM D6319 - 10(2015)	Meets	Meets	Similar
Thickness – Finger - Palm	ASTM D6319 - 10(2015)	Meets	Meets	Similar
Powder Content	ASTM D6124 - 06(2011) (≤ 2 mg/glove)	Meets	Meets	Similar

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate				
Chemotherapy Drug Permeation Test	ASTM D6978-05			
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
Cisplatin	1.0 mg/ml	>240	>240	Similar – The chemotherapy drugs tested have similar breakthrough detection times; the drugs with low permeation times are the same.
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	
Fentanyl Citrate Injection	100mcg/2ml	-	>240	
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		
		K183287	K192954	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
	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
	Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	-	Exhibits severe cytotoxicity reactivity at 100%, and 66% extract concentrations and no cytotoxicity reactivity at 44%, 30%, 20% and 15% extract concentrations under the condition of this test.	-Different
	Acute systemic toxicity study ISO 10993-11: 2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	-	Passes Under the conditions of the study, the subject showed no adverse biological reaction.	-Different
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes	Passes	Same
Indication for Use		A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with	The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical	Similar

		chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum Breakthrough Detection Time in minutes Carmustine (BCNU) (3.3mg/ml) - 10.1 Cisplatin, (1.0 mg/ml) - ≥ 240 Cyclophosphamide (Cytoxan), 20.0 mg/ml - ≥ 240 Cytarabine (100 mg/ml) - ≥ 240 Dacarbazine (DTIC), 10.0 mg/ml - ≥ 240 Doxorubicin Hydrochloride, (2.0 mg/ml) - ≥ 240 Etoposide, (20.0 mg/ml) - ≥ 240 Fluorouracil, (50.0 mg/ml) - ≥ 240 Ifosfamide (50.0 mg/ml) ≥ 240 Methotrexate (25.0 mg/ml) ≥ 240 Mitomycin C (0.5 mg/ml) ≥ 240 Mitoxantrone (2.0 mg/ml) ≥ 240 Paclitaxel (Taxol), 6.0 mg/ml - ≥ 240 Thiotepa (10.0 mg/ml) - 30.2 Vincristine Sulfate (1.0 mg/ml) ≥ 240. Please note that Carmustine (BCNU) has extremely low permeation time of 10.1 minutes. Fentanyl Citrate and Concertation Fentanyl Citrate Injection (100.0 mcg/2ml)	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 and Fentanyl Citrate. Tested for use with chemotherapy drugs and Fentanyl Citrate. Tested chemotherapy 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 The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 18.2 minutes and Thiotepa: 57.3 minutes. Warning: Do not use with Carmustine.	

		Minimum Breakthrough Detection Time in minutes ≥ 240	Tested Fentanyl Citrate is as follows: Average Breakthrough Detection Time (minutes) Fentanyl Citrate Injection 100.0 mcg/2ml ≥ 240	
Material	ASTM D6319 - 10(2015)	Nitrile	Nitrile	Same
Color	-	Blue White Black	Blue	Same
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:

Methodology	Purpose	Acceptance Criteria	Results
ASTM D412-2016	Physical Properties	Tensile Strength (Min 14 Mpa) and Elongation (Min 400%)	Pass
ASTM D5151-2006	Water leak test	AQL 1.5 (ISO 2859-1)	Pass
ASTM D6124-2006	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-2005	Permeation by Chemotherapy Drugs	≥ 240 minutes	Pass
ISO 10993-10	Irritation and delayed-type hypersensitivity	Skin sensitization and Skin irritation	The subject device is non-sensitization and Non-irritation
ISO 10993-5	Cytotoxicity	Cytotoxicity reactivity	Exhibits severe cytotoxicity reactivity at 100%, and 66% extract concentrations and no cytotoxicity reactivity at 44%, 30%, 20% and 15% extract concentrations under the condition of this test.
ISO 10993-1:2018	Acute systemic toxicity study	Subject showed no adverse biological reaction	No adverse biological reaction.

- ASTM D412-2016 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- 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 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 subject device is as safe, as effective, and performs as well as the legally marketed device.