August 29, 2022

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

Re: K200181
Trade/Device Name: Black Colored, Powder Free Nitrile Examination Gloves, Non-sterile, 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

Dear Ng 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 April 15, 2020. Specifically, FDA is updating this SE Letter for a typographical error contained in the Indications for Use, 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

April 15, 2020

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

Re: K200181
Trade/Device Name: Black Colored, Powder Free Nitrile Examination Gloves, Non-sterile, 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
Dated: January 22, 2020
Received: January 24, 2020

Dear Ng 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,

FDA Elizabeth F. Claverie -S

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K200181

Device Name

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

Indications for Use *(Describe)*

The Black Colored, Power 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. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested for use 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
*Carmustine (BCNU) 3.3mg.ml	54.1 (minutes)
*Thiotepa 10.0 mg/ml	6.0 (minutes)

*Please note that these drugs have extremely low permeation time
CAUTION: Testing showed an average breakthrough time of 54.1 minutes with Carmustine.
WARNING: Do not use with Thiotepa.

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

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

K200181

Prepared according to 21 CFR § 807.92
Preparation Date: April 10, 2020

1. Submitter

Name: Comfort Rubber Gloves Industries Sdn. Bhd.

Address: Lot 821, Jalan Matang, 34750 Matang, Perak, Malaysia.

Phone No.: 605-847 2777

Fax No.: 605-847 9108

Contact Person: Ng Kok Howe (Mr.)

2. Identification of the Device

Device name: Black Colored, Power 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

Regulation: 21 CFR 880.6250

Product code: LZA

Classification Name: Patient Examination Gloves Specialty

Regulation: 21 CFR 880.6250

Product code: LZC

3. Identification of the Legally Marketed Device as Predicate

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.

Predicate 510(K) No.: K183287

4. Description of the Device:

Black Colored, Power Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate meets the requirements of ASTM D6319-10(2015) Standard Specification for Nitrile Examination Gloves for Medical Application.

Table 1. Glove Specifications for different models

Reference Standard	Glove size	Standard Requirements	
		Palm width (mm)	Length (mm)
ASTM 6319	XS	75 ± 5mm	Min 240
	S	85 ± 5mm	
	M	95 ± 5mm	
	L	105 ± 5mm	
	XL	115 ± 5mm	

5. Indications for Use

The Black Colored, Power Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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 and Fentanyl Citrate. Tested for use with chemotherapy drugs and fentanyl citrate.

6. Comparison of the Technological Characteristics between the Subject and Predicate Devices

The Black Colored, Power 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 the predicate.

Table 2. Comparison of the Technological Characteristics

Characteristics	Standards	Device performance		Remarks
		Predicate device	Subject device	
Manufacturer(s)		Kossan International Sdn. Bhd.	Comfort Rubber Gloves Industries Sdn. Bhd	-
510(k) number		K183287	K200181	-
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 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	The Black Colored, Power 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. 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:	Same

		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 lfosfamide (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 (1.0mg/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) Minimum Breakthrough Detection Time in minutes>=240	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, 50.0mg/ml - >=240 Paclitaxel (Taxol), 6.0mg/ml >=240 *Carmustine (BCNU) 3.3mg/ml - 54.1 (mins) *Thiotepa 10.0 mg/ml - 16.0 (mins) *Please note that these drugs have extremely low permeation time. CAUTION: Testing showed an average breakthrough time of 54.1 minutes with Carmustine; WARNING: Do not use with Thiotepa. Tested Fentanyl Citrate is as follows: Fentanyl Citrate Injection 100.0 mcg/2ml Average Breakthrough Detection Time (minutes) >=240	
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)	Meets	Meets	Similar
Chemotherapy Drugs	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
Cisolatin	1.0 mg/ml	>240	>240	Same
Cyclophosphamide (Cvtoxan)	20 mg/ml	>240	>240	Same
Dacarbazine (DTIC)	10.0 mg/ml	>240	>240	Same
Doxorubicin Hvdrochloride	2 0 mg/ml	>240	>240	Same
Etoooside (Toposar)	20.0 ma/ml	>240	>240	Same
Fluorouracil	50.0 ma/ml	>240	>240	Same
Paclitaxel (Taxol)	6.0 mg/ml	>240	>240	Same
lfosfamide	50.0 ma/ml	>240	-	Different
Mitoxantrone	2.0 mg/ml	>240	-	Different
Vincristine Sulfate	1.0 mg/ml	>240	-	Different
Carmustine (BCNU)	3.3 mg/ml	15.0	54.1	Similar

Thiotepa	10.0 mg/ml	2.0	16.0	Similar
Fentanyl Citrate	100mcq/2ml	-	>240	Different
Biocompatibility	ISO10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin Sensitization	Under the conditions of the study, the subject device is non-irritating	Under the conditions of the study, the subject device is non- irritating	Same
		Under the conditions of the study, the subject device is non- sensitization	Under the conditions of the study, the subject device is non- sensitization	Same
	ISO10993-5: 2009 Biological Evaluation of Medical Devices- Part 5: Test for In Vitro Cytotoxicity	Under the conditions of the study, the subject device is non- cytotoxic	Under the conditions of the study, the subject device is non-cytotoxic	Same
Watertight (1000ml)	21 CFR 800.20 ASTM D5151	Passes	Passes	Same
Material	ASTM 06319 - 10(2015)	Nitrile	Nitrite	Same
Color	-	Blue White Black	Black	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

The subject device and the predicate device 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.

7. Summary of Non-Clinical tests

Non-clinical tests were conducted to demonstrate that the proposed device met 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

Table 3. Quality Assurance Testing For Finished Gloves

Characteristics	Reference Test Method &Sampling	Inspection Level	AQL	Acceptance Criteria
Dimension (length, width, thickness)	ASTM D6319 - 10(2015) ANSI / ASQC 21.4-2003	S-2	4.0	Meet Acceptance Number
Tensile strength and Ultimate elongation	ASTM D 6319 - 10(2015) ANSI / ASQC 21.4-2003	S-2	4.0	Meet Acceptance Number
Water Leak	FDA 1000ml water leak test method (21CFR 800.20) ANSI / ASQC 21 .4-2003	G-1	1.5	Meet Acceptance Number
Powder Residue	ASTM D6124 - 06(2011)	N/A	N/A	2 mg/glove

Table 4. Physical Property

Sample	Unaged		Aged (7 Days, 70°C)	
	Tensile Strength (MPA)	Elongation At Break (%)	Tensile Strength (MPA)	Elongation At Break (%)
1	22.86	596	20.80	447
2	15.32	520	19.73	462
3	16.79	523	24.81	518
4	15.81	575	20.49	459
5	23.60	585	24.92	518
6	22.00	550	20.49	487
7	21.36	531	20.94	475
8	20.78	637	20.47	499
9	22.95	602	19.03	459
10	22.11	541	24.29	493
11	21.23	615	16.44	427
12	20.43	552	19.88	466
13	22.84	633	19.13	487
Mean	21.36	585	20.49	475
Minimum	15.32	520	16.44	427

Table 5. Freedom From Holes

Test	Number Tested/Batch	Results
Tensile Strength	13	Pass (Minimum 16.44 MPa)
Ultimate Elongation	13	Pass (Minimum 427 %)
Freedom From Holes	80	Pass (No. Of Defective = 0)

Table 6. Powder Residual Test Result

No	Sample	Size	Length (mm)	Weight of Filter+ Dried Residue (A)	Weight of Filter (B)	Weight of H20 + Dried Residue (C)	A-B-C X 1000 (mg)	Residual Powder Content (mg/glove)
1	Lot No. 81107F50510	M	240	0.0970	0.0945	0.0000	2.5	0.50

Table 7. Chemotherapy Drug Permeation Test Results

Test Chemotherapy Drugs	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)	Steady State Perm. Rate (Specimen 1/2/3) (µg/Cm2/Minute)	Other Observations
Carmustine (BCNU), 3.3 mg/ml (3,300ppm)	54.1 (56.4, 54.1, 56.7)	0.6 (0.6, 0.6, 0 .6)	Moderate swelling and slight degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240	N/A	No significant changes
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	>240	N/A	No significant changes
Dacarbazine, 10 mg/ml (10,000 ppm)	>240	N/A	No significant Changes
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	>240	N/A	No significant changes
Etoposide (Toposar), 20.0 mg/ml (20 000 ppm)	>240	N/A	No significant changes
Fluorouracil, 50 mg/ml (50,000ppm)	>240	N/A	No significant changes
Paclitaxel (Taxol), 6.0 mg/ml (6,000ppm)	>240	N/A	Slight swelling and no degradation
Thiotepa (THT), 10 mg/ml (10,000ppm)	16.0 (16.0,26.8,17.7)	0.4 (0.5,0.3,0.4)	No significant changes

Table 8. Fentanyl Drug Permeation Test Result

Test Drug And Concentration	Minimum Breakthrough Detection Time (Specimen 1/2/3) (Minutes)	Steady State Perm. Rate (Specimen 1/2/3) (µg/Cm2/Minute)	Other Observations
Fentanyl Citrate Injection, 100mcg/2mL	>240	N/A	Slight swelling; no degradation

8. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, the Black Colored, Power Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under 510(K) submission K183287.