March 30, 2023

Professional Latex Sdn Bhd
Kok Yoon Lim
Managing Director
Lot 20734 & 20735, Lengkungan Perusahaan Kamunting 3/1
Kawasan Perusahaan Kamunting Raya, Kamunting, Perak Darul Ridzuan 34600
Malaysia

Re: K220088
Trade/Device Name: Powder Free Nitrile Examination Glove, Non-Sterile, and 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, OPJ, QDO
Dated: January 5, 2023
Received: March 2, 2023

Dear Kok Lim:

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,

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

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)* K220088

Device Name

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

Indications for Use *(Describe)*

Powder Free Nitrile Examination Gloves, Non-Sterile, and tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam gloves which is 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 and Concentration:	Minimum Breakthrough Detection Time (minutes)
Cisplatin, 1.0 mg/ml	> 240
Cyciophosphamide (Cytoxan), 20.0 mg/ml	> 240
Dacarbazine, 10.0 mg/ml	> 240
Doxorubicin HCI, 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, 6.0 mg/ml	> 240
Vincristine Sulfate, 1.0 mg/ml	> 240
Carmustine (BCNU), 3.3 mg/ml	24.3
ThioTepa, 10.0 mg/ml	48.6
Fentanyl Citrate Injection 100.0 mcg/2ml	> 240

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

Carmustine (BCNU), 3.3 mg/ml : 24.3 minutes and Thiotepa, 10.0 mg/ml : 48.6 minutes
Do not use with Carmustine and Thiotepa

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 K220088

1.0 Submitter

Professional Latex Sdn Bhd
Lot Plant 2: Lot 20734 & 20735, Lengkungan Perusahaan Kamunting 3/1, Kawasan Perusahaan Kamunting Raya, 34600 Kamunting, Perak Darul Ridzuan, Malaysia.

Tel: +605 891 6650
Name Of Contact Person: Foong Kah Kah
Email Address: foongkk@professionallatex.com
Date of Summary Prepared: 25 March, 2023

2.0 Name of Device

Trade Name:

Powder Free Nitrile Examination Glove, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

510(K) Number:	K220088
Classification Name:	Polymer Patient Examination Glove
	Patient Examination Gloves, Specialty
	Fentanyl And Other Opioid Protection Glove
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Device Class:	I
Product Code:	LZA, LZC, OPJ, QDO

3.0 Identification of The Legally Marketed Device

Predicate Device Name:

Blue Colored, Powder Free Nitrile Patient Examination Glove, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.

Company:	Comfort Rubber Gloves Industries Sdn. Bhd
Predicate 510(K) Number:	K192954

4.0 Description of Device

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 Standard Specification for Nitrile Examination Gloves for Medical Application. The principal operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the-counter single use. It is an ambidextrous, light blue colour device with wide range of sizes, i.e (XS, S, M, L and XL). It is designated for single use only.

5.0 Intended Use/Indications for Use of Glove

Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam gloves 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:

	Minimum Breakthrough Detection Time (Minutes)
Cisplatin, 1.0 mg/ml	> 240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	> 240
Dacarbazine, 10.0 mg/ml	> 240
Doxorubicin HCI, 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, 6.0 mg/ml	> 240
Vincristine Sulfate, 1.0 mg/ml	> 240
Carmustine (BCNU), 3.3 mg/ml	24.3
ThioTepa, 10.0 mg/ml	48.6
Fentanyl Citrate Injection 100.0mcg/2ml	> 240

WARNING.

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU), 3.3mg/ml : 24.3 minutes and ThioTepa, 10.0mg/ml : 48.6 minutes.

Do not use with Carmustine and ThioTepa.

6.0 Summary of the Technologies Characteristic of the Device compared to the Predicate Device

Powdered 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 D6139-10 Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards as shown in table.

Table 1: Technological Characteristic Comparison Table

Characteristics	510(K) Number / Standards	Device Performance		Comparison Result
		Predicate device K192954	**Subject device** K220088	
Regulation Number		21 CFR 880.6250	21 CFR 880.6250	Same.
Product Code		LZA, LZC, QDO	LZA, LZC, QDO,OPJ	Similar
Material	ASTM-D6319-10	Synthetic Nitrile rubber	Synthetic Nitrile rubber	Same.
Size	ASTM-D6319-10	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same.
Physical Dimension	ASTM-D6319-10	Length: Min 240mm Thickness Palm & finger: Min: 0.05 Width by sizes: XS - 70mm S - 80mm M - 95mm L - 110mm XL - 120mm Tolerance: ± 10mm	Length Min: 240mm Thickness Palm & finger: Min: 0.05 Width by sizes: XS - 70mm S - 80mm M - 95mm L - 110mm XL – 120mm Tolerance: ± 10mm	Similar Meeting the requirements of Dimension under ASTM-D6319-10.
Physical Properties	ASTM-D6319-10	Tensile Strength Before Aged: Min: 14MPa After Aged: Min: 14MPa Ultimate Elongation: Before aged: Min 500% After aged: Min 400%	Tensile Strength Before Aged: Min: 14MPa After Aged: Min: 14MPa Ultimate Elongation: Before aged: Min 500% After aged: Min 400%	Similar Meeting the requirements of physical properties under ASTM-D6319-10.

Powder Content	ASTM-D6124-06(2017)	Powder Amount: ≤ 2mg	Powder Amount: ≤ 2mg	Similar Meeting the requirements of Powder Content under ASTM-D6124-06(2017).
Freedom from Holes (Watertight @1000ml)	21 CFR 800.20 ASTM D5151	Meets ASTM D6139-10 and ASTM D5151-06 requirements of AQL 2.5	AQL .2,5	Similar Meeting the freedom from holes requirement under ASTM-D5151
Color	No standards requirements	Blue	Blue	Similar Both are similar in color
Single Use	Designated as single use gloves	Single use	Sigle use	Same. Both are single use gloves.
Sterility	Designated as non-sterile gloves	No sterility report as sold as non-sterile	No sterility report as sold as non-sterile	Same. Both are non-sterilized Gloves

Table 2: Powder Free Examination Gloves, Non-sterile, and tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Characteristics	Standard	510(K) Number	Device Performance		Comparison result
Chemotherapy Drugs Permeation Test	ASTM D6978-05		**Predicate device**	**Subject device** K220088	
Chemotherapy Drug	Concentration mg/ml		Minimum Breakthrough Detection Time (Minutes)		
Cisplatin	1.0		≥ 240	> 240	Similar The chemotherapy drugs tested have similar breakthrough detection times and
Cyclophosphamide (Cytoxan)	20.0		≥ 240	> 240	
Dacarbazine	10.0		≥ 240	> 240	
Doxorubicin HCI	2.0		≥ 240	> 240	
Etoposide	20.0		≥ 240	> 240	

Fluorouracil	50.0	≥ 240	> 240	drug with low permeation time.
Ifofamide	50.0	-	> 240	
Methotrexate	25.0	-	> 240	
Mitomycin C	0.5	-	> 240	
Mitoxantrone	2.0	-	> 240	
Paclitaxel	6.0	≥ 240	> 240	
Vincristine Sulfate	1.0	-	> 240	
*Carmustine (BCNU)	3.3	18.2	24.3	
*ThioTepa	10.0	57.3	48.6	
Fentanyl Citrate Injection	*100 mcg/2ml	≥ 240	> 240	

Characteristic	510(K) Number	Device Performance		Comparison result
		Predicate device K192954	**Subject device** K220088	
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, 3.3 mg/ml: 24.3 minutes and* *ThioTepa,10.0mg/ml : 48.6 minutes* *Do not use with Carmustine and ThioTepa*	Similar The chemotherapy drugs tested have similar breakthrough detection times and the drug with low permeation time.

Table 3: Biocompatible Characteristic & Indication for Use Comparison Table

Characteristics	510(K) Number / Standards	Device Performance		Comparison result
		Predicate device K192954	**Subject device** K220088	
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010	Passed. Under the conditions of the study, the subject device is non-Irritating	Passed. Under the conditions of the study, the subject device is non-irritating	Same. Both are tested to be non-irritant.
	Dermal Sensitization ISO 10993-	Passed. Under the condition of the study, the	Passed. Under the condition of the study, the	Same. Both are tested to be non-sensitizer

	10: 2010	subject device is non-sensitizer	subject device is non-sensitizer	
	Cytotoxicity ISO 10993-5: 2009	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.	It is concluded that, undiluted, 1:2 and 1:4 dilution is cytotoxicity and the dilution 1:8 and 1:16 and 1:32 us non-cytotoxic.	Same
	Acute Systemic toxicity ISO 10993-11: 2017	Under the condition of the study, no evidence of systemic toxicity	Under the conditions of the study, the subject showed no adverse biological reaction	Same. Both are tested to be non-systemic toxicity

Characteristics	Device Performance		Comparison result
Indication for Use	**Predicate device** 510(K) Number: K192954	**Subject device** 510(K) Number: K220088	
	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 gloves 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:	Powder free Nitrile Examination Gloves, Non-Sterile and tested for use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam gloves which is a disposal device intended for medical purposes that is worn on the examiners' 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	Similar Both indication for use is similar.

	Average Breakthrough Detection Time (minutes) Cisplatin 1.0 mg/ml - ≥ 240 Cyclophosphamide (Cytoxan) (20.0 mg/ml) - ≥ 240 Dacarbazine (DTIC) (10.0mg/ml) - ≥ 240 Doxorubicin Hydrochlorine (2.0mg/ml) - ≥ 240 Etoposide (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 Thiotepa (THT) 10.0mg/ml 57.3 Tested Fentanyl Citrate is as follows : Average Breakthrough Detection Time (minutes) Fentanyl Citrate Injection 100.0 mg/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	Tested Chemotherapy Drugs and Concentration Minimum Breakthrough Detection Times (Minutes) Cisplatin 1.0mg/ml - > 240 Cyciophosphamide (Cytoxan) 20.0mg/ml - > 240 Dacarbazine 10.0mg/ml - > 240 Doxorubicin HCI 2.0mg/ml - > 240 Etoposide 20.0mg/m - > 240 Fluorouracil 50.0mg/ml - > 240 Ifosfamide 50.0mg/ml - > 240 Methotrexate 25.0mg/ml - > 240 Mitomycin C 0.5mg/ml - > 240.0 Mitoxantrone 20.0mg/ml - > 240 Paclitaxel – 6.0mg/ml > 240 Vincristine Sulfate - > 240 Carmustine (BCNU) 3.3mg/ml – 24.3 Thiotepa 10.0mg/ml - 48.6 Fentanyl Citrate Injection (100mcg/2ml) - > 240 WARNING. Please note that the following drugs have extremely low permeation time: Carmustine (BCNU) 3.3 mg/ml 24.3 minutes and Thiotepa 10.0mg/ml 48.6 minutes Do not use with Carmustine and Thiotepa	

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 result demonstrated that the proposed device met the performance criteria with the following standards:

Standard	Purpose	Acceptance Criteria	Result / Conclusion
ASTM D6319-10	Physical Dimension	Length: Min 240mm Thickness Palm & finger: Min 0.05mm Width by sizes: XS - 70mm S - 80mm M - 95mm L - 110mm Tolerance: ± 10mm	Passed
ASTM - D6319-10	Physical Properties	Tensile Strength Before Aged: Min: 14MPa After Aged: Min: 14MPa Ultimate Elongation: Before aged: Min 500% After aged: Min 400%	Passed
ASTM D6124-06 (2017)	Powder Residual	Powder Amount: < 2mg	Passed
ASTM D5151-19	Freedom from Holes (Watertight @1000ml)	AQL 2.5	Passed
ISO 10993-10:2010	Irritation and delayed-type hypersensitivity	No Skin sensitization and irritation	No skin sensitization and irritation, Passed
ISO 10993-5: 2009	Cytotoxicity	No Cytotoxicity Reaction	Cytotoxicity reaction, Failed

<table>
<tr><td>ISO 10993-11: 2017</td><td>Acute Systemic toxicity</td><td>No adverse biological reaction</td><td>Passed</td></tr>
<tr><td>ASTM D6978</td><td>Chemical Permeation</td><td colspan="2">
<table>
<tr><th>Chemotherapy Drugs</th><th>Concentration (mg/ml)</th><th>Breakthrough Time In Minutes</th><th>Observation</th></tr>
<tr><td>Cisplatin</td><td>1.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Cyciophosphamide</td><td>20.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Dacarbazine</td><td>10.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Doxorubicin HCI</td><td>2.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Etoposide</td><td>20.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Fluorouracil</td><td>50.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Ifosfamide</td><td>50.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Methotrexate</td><td>25.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Mitomycin C</td><td>0.5</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Mitoxantrone</td><td>2.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Paclitaxel</td><td>6.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
<tr><td>Vincristine Sulfate</td><td>1.0</td><td>> 240</td><td>Slight swelling and no degradation</td></tr>
</table>
</td></tr>
</table>

		Carmustine (BCNU)	3.3	24.3 (25.3,27.4,24 .3)	Moderate swelling and no degradation
		ThioTepa	10.0	48.6 (49.2, 58.1, 48.6)	Moderate swelling and no degradation
		Fentanyl Citrate	100mcg/ml	> 240	Slight swelling and no degradation

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

- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6319-10 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6978-2005(2019) Standard Practice for Assessment of Resistances of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-5 Biological evaluation of medical devices Part 5 – Tests for In Vivo Cytotoxicity
- ISO 10993-10 – Biological evaluation of medical devices Part 1- - Tests for irritation and delayed-type hypersensitivity.

8.0 Clinical Performance Data

Not needed.

9.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.