April 17, 2022

Meditech Gloves SDN BHD
Wan Hassan
Assistant Manager- QA/RA
PT 3345, Jalan Permata 1/3, Arab Malaysian Industrial Park
Nilai, Negeri Sembilan 71800
Malaysia

Re: K213408
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue) 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: March 12, 2022
Received: March 22, 2022

Dear Wan Hassan:

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, M.D., Ph.D.
Acting 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213408

Device Name
Powder Free Nitrile Patient Examination Gloves, Non-Sterile
(Blue) tested for use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
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.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration Minimum Breakthrough Detection Time (Minutes)
Azacitidine, 25mg/ml (25,000 ppm) >240mins
Bleomycin Sulphate 15mg/ml (15,000 ppm) >240mins
Carboplatin 10mg/ml (10,000 ppm) >240mins
Carmustine (BCNU) 3.3mg/ml (3300 ppm) 22.5mins
Cetuximab 2mg/ml (2000 ppm) >240mins
Cisplatin 1mg/ml (1000 ppm) >240mins
Cyclophosphamide (Cytoxan) 20mg/ml (20,000 ppm) >240mins
Dacarbazine 10mg/ml (10,000 ppm) >240mins
Docetaxel 10mg/ml (10,000 ppm) >240mins
Doxorubicin HCl 2mg/ml (2,000 ppm) >240mins
Ellence (Epirubicin) 2mg/ml (2,000 ppm) >240mins
Etoposide 20mg/ml (20,000 ppm) >240mins
Fluorouracil 50mg/ml (50,000 ppm) >240mins
Gemcitabine 38mg/ml (38,000 ppm) >240mins
Ifosfamide 50mg/ml (50,000 ppm) >240mins
Irinotecan 20mg/ml (20,000 ppm) >240mins
Methotrexate 25mg/ml (25,000ppm) >240mins
Mitomycin C 0.5mg/ml (500 ppm) >240mins
Mitoxantrone 2mg/ml (2,000 ppm) >240mins
Oxaliplatin 2mg/ml (2,000ppm) >240mins
Paclitaxel 6mg/ml (6,000 ppm) >240mins
Rituximab 10mg/ml (10,000 ppm) >240mins
Thio Tepa 10 mg/ml (10,000 ppm) 36.1 mins
Vincristine Sulfate 1mg/ml 1,000 ppm) >240mins
Vinorelbine 10mg/ml (10,000 ppm) >240mins
Tested for Fentanyl Citrate is as follows:
Fentanyl Citrate 100mcg/2ml >240mins

Please note the following drugs have low permeation times
Camustine (BCNU) 3.3mg/ml 22.5mins
Thio Tepa 10mg/ml 36.1mins

Warning: Do not use these gloves with Camustine or Thio Tepa.

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 K213408

1.0 Submitter:

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Phone No.: +60 6 799 7742
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Date of Summary Prepared: April 15, 2022

2.0 Name of the device:

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

Common Name: Examination Gloves
Classification Name: Patient Examination Gloves (21 CFR 880.6250 product code LZA, LZC, QDO)

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

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

510(k)	:	K192954
Regulatory	:	Class I
Product Code	:	LZA, LZC, QDO

4.0 Description of The Device:

Powder Free Nitrile Patient Examination Glove, Non-Sterile (Blue) meet all the requirements of ASTM standard D6319-19 and FDA 21 CFR 880.6250.

The powder free nitrile examination glove is manufactured from synthetic rubber latex. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is ambidextrous, i.e., can be worn on right hand or left hand.

5.0 Intended Use of the Device:

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.

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These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	**Minimum Breakthrough Detection Time (Minutes)**
Azacitidine, 25mg/ml (25,000 ppm)	>240mins
Bleomycin Sulphate 15mg/ml (15,000 ppm)	>240mins
Carboplatin 10mg/ml (10,000 ppm)	>240mins
Carmustine (BCNU) 3.3mg/ml (3300 ppm)	**22.5mins**
Cetuximab 2mg/ml (2000 ppm)	>240mins
Cisplatin 1mg/ml (1000 ppm)	>240mins
Cyclophosphamide (Cytoxan) 20mg/ml (20,000 ppm)	>240mins
Dacarbazine 10mg/ml (10,000 ppm)	>240mins
Docetaxel 10mg/ml (10,000 ppm)	>240mins
Doxorubicin HCl 2mg/ml (2,000 ppm)	>240mins
Ellence (Epirubicin) 2mg/ml (2,000 ppm)	>240mins
Etoposide 20mg/ml (20,000 ppm)	>240mins
Fluorouracil 50mg/ml (50,000 ppm)	>240mins
Gemcitabine 38mg/ml (38,000 ppm)	>240mins
Ifosfamide 50mg/ml (50,000 ppm)	>240mins
Irinotecan 20mg/ml (20,000 ppm)	>240mins
Methotrexate 25mg/ml (25,000ppm)	>240mins
Mitomycin C 0.5mg/ml (500 ppm)	>240mins
Mitoxantrone 2mg/ml (2,000 ppm)	>240mins
Oxaliplatin 2mg/ml (2,000ppm)	>240mins
Paclitaxel 6mg/ml (6,000 ppm)	>240mins
Rituximab 10mg/ml (10,000 ppm)	>240mins
Thio Tepa 10 mg/ml (10,000 ppm)	**36.1 mins**
Vincristine Sulfate 1mg/ml 1,000 ppm)	>240mins
Vinorelbine 10mg/ml (10,000 ppm)	>240mins

Tested for Fentanyl Citrate is as follows:

Fentanyl Citrate 100mcg/2ml	>240mins

Please note the following drugs have low permeation times
Camustine (BCNU) 3.3mg/ml 22.5mins
Thio Tepa 10mg/ml 36.1mins

Warning: Do not use these gloves with Camustine or Thio Tepa.

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6.0 Comparison of the Technological Characteristics with the Predicate Device:

The Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue) are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards of the subject gloves to the predicate device

CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE	CURRRENT	
		BLUE	BLUE	
510(k) Number		K192954	K213408	
Manufacturer(s)	-	Comfort Rubber Gloves Industries Sdn. Bhd.	Meditech Gloves Sdn Bhd	
Material	ASTM D6319-19	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger textured	Finger textured	Same
Physical Properties	ASTM D6319-19	Meets	Meets	Same
Thickness - Finger - Palm	ASTM D6319-19	Min 0.05mm Min 0.05mm	0.07– 0.10mm 0.06– 0.09mm	Similar
Width	ASTM D6319-19 XS 70±10mm S 80±10mm M 95±10mm L 110±10mm XL >110mm	XS Not Provided S Not Provided M Not Provided L Not Provided XL Not Provided	XS 70–75mm S 80–86mm M 93–97mm L 102–106mm XL 114–116mm	Different
Length	ASTM D6319-19	Min 240mm	Min 240mm	Same
Powder Free	ASTM D6124-06	≤ 2 mg/glove	≤ 2 mg/glove	Same

CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE BLUE	CURRRENT BLUE	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010	Passes Under the conditions of the stud, the subject device is non-irritating	Passes (Not a primary skin irritant) There was no erythema or oedema noted on test site after (1±0.1), (24±2), (48±2) and (72±2) hours. The primary Irritation Index (PII) was "0". Also, no mortality after 72 hours. The gloves considered negligible.	Similar
Biocompatibility	Dermal Sensitization- ISO 10993-10:2010	Passes Under the conditions of the stud, the subject device is non-sensitizing .	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0, 24 hours and 48 hours) in animals treated with the test material and negative control.	Similar
Biocompatibility	Cytotoxicity – MEM Elution, ISO 10993-5:2009	Exhibit severe cytotoxicity reactivity at 100% and 66% extract concentration and no cytotoxicity at 44%,30%, 20% and 15% extract concentration under the condition of this test.	Exhibit severe cytotoxicity reactivity at 100%, 50%, and 25% extract concentration. No cytotoxicity reactivity at 12.5%, 6.25% and 3.125% extract concentrations.	Similar

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CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Passes Under the conditions of the study, the subject showed no adverse biological reaction.	Passes (no adverse biological reaction) No mortality was observed (72±2) hours	Same
Watertight (1000ml)	ASTM D6319-19 & ASTM D5151	Passes at AQL 1.5	Passes at AQL 1.5	Same
Indication for 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. These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	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. These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Same

CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
Chemotherapy Drugs Permeation Test ASTM D6978-05 (Reapproved 2019)				
Chemotherapy Drug and Concentration	**ASTM D6978-05 (Reapproved 2019)**	**Minimum Breakthrough Detection Time (Minutes)**		
Azacitidine, 25mg/ml (25,000 ppm)		-	>240mins	Different
Bleomycin Sulphate 15mg/ml (15,000 ppm)		-	>240mins	Different
Carboplatin 10mg/ml (10,000 ppm)		-	>240mins	Different
Carmustine (BCNU) 3.3mg/ml (3300 ppm)		18.32mins	**22.5mins**	Similar
Cetuximab 2mg/ml (2000 ppm)		-	>240mins	Different
Cisplatin 1mg/ml (1000 ppm)		>240mins	>240mins	Same
Cyclophosphamide (Cytoxan) 20mg/ml (20,000 ppm)		>240mins	>240mins	Same
Dacarbazine 10mg/ml (10,000 ppm)		>240mins	>240mins	Same
Docetaxel 10mg/ml (10,000 ppm)		-	>240mins	Different
Doxorubicin HCl 2mg/ml (2,000 ppm)		>240mins	>240mins	Same
Ellence (Epirubicin) 2mg/ml (2,000 ppm)		-	>240mins	Different
Etoposide 20mg/ml (20,000 ppm)		>240mins	>240mins	Same

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CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
Fluorouracil 50mg/ml (50,000 ppm)		>240mins	>240mins	Same
Gemcitabine 38mg/ml (38,000 ppm)		-	>240mins	Different
Ifosfamide 50mg/ml (50,000 ppm)		>240mins	>240mins	Same
Irinotecan 20mg/ml (20,000 ppm)		-	>240mins	Different
Methotrexate 25mg/ml (25,000ppm)		>240mins	>240mins	Same
Mitomycin C 0.5mg/ml (500 ppm)		>240mins	>240mins	Same
Mitoxantrone 2mg/ml (2,000 ppm)		>240mins	>240mins	Same
Oxaliplatin 2mg/ml (2,000ppm)		-	>240mins	Different
Paclitaxel 6mg/ml (6,000 ppm)		>240mins	>240mins	Same
Rituximab 10mg/ml (10,000 ppm)		-	>240mins	Different
Thio Tepa 10 mg/ml (10,000 ppm)		**57.3mins**	**36.1mins**	Different
Vincristine Sulfate 1mg/ml 1,000 ppm)		>240mins	>240mins	Same
Vinorelbine 10mg/ml (10,000 ppm)		-	>240mins	Different
Warning		Do Not Use with Camustine	Do Not Use with Camustine or Thio Tepa.	Different
Fentanyl Citrate 100mcg/2ml		>240mins	>240mins	Same

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CHARACTERISTICS	STANDARDS	DEVICE COMPARISONS		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
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

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods.

However, the current glove is tested to many more chemotherapy drugs than the predicate and has passed the minimum penetration time of 240 minutes.

7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical tests for this powder free nitrile patient examination gloves is summarized as per below.

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results		Status
				Before aging	After aging	Before aging	After aging	
Physical Properties	ASTM D412-16 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension)	To evaluate the tensile (tension) properties of glove.	Tensile Strength	Min 14 MPa	Min 14 MPa	14.4	16.3	Pass
			Ultimate Elongation	Min 500%	Min 400%	506	402	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria		Results		Status
Dimension	ASTM D3767-03(2020) Standard Practice for Rubber – Measurement of Dimensions	To measure the length, width, and thickness of glove	Length	Min 240mm	Min 240		Pass
			Width:				
			XS	70 ± 10 mm	Ave = 72 mm		Pass
			S	80 ± 10 mm	Ave = 83 mm		Pass
			M	95± 10 mm	Ave = 95 mm		Pass
			L	110 ± 10 mm	Ave = 104 mm		Pass
			XL	>110	Ave = 115 mm		Pass
			Thickness	Finger – 0.05mm Palm – 0.05mm	Thickness	Finger – 0.08mm Palm – 0.05mm	Pass

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Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Water Tight	ASTM D 5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To detect holes that leak water and thereby compromise the usefulness of the glove	Sample Size : 500 Inspection Level : GI AQL : 1.5 Acceptance No : 14	This batch sampling is 500,001 and over. Hence according to single sampling plan GI, the sample to be drawn is under Code M equivalent to 500 pieces with accept 14 and reject 15. During the test, 12 pieces were found with leaks. Hence it falls within the acceptance criteria.	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Residual Powder	ASTM D6124-06 (2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the amount of residual powder and non-powder solids found on gloves	Less than 2 mg per glove	Sample size : 5 pcs Requirement : <2mg/glove Result : 1.5 mg/glove	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Permeation by Chemotherapy Drugs	ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	To determine the minimum breakthrough Detection Time	≥240mins	≥240mins **Except for Camustine and Thio Tepa**	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Biocompatibilty Primary Skin Irritation	ISO 10993-10:2010	To demonstrates the irritation potential of the gloves, i.e., for initiating or aggravating damage through its contact with the skin	Not a primary skin irritant under the condition of this test.	Not a primary skin irritant There was no erythema or oedema noted on test site after (1±0.1), (24±2), (48±2) and (72±2) hours. The primary Irritation Index (PII) was "0". Also, no mortality after 72 hours. The gloves considered negligible.	Pass
Biocompatibilty Dermal Sensitization	ISO 10993-10:2010	To demonstrate the potential of the device for eliciting a delayed hypersensitivity (Type IV) immunologic response through its contact with the skin.	Not a contact sensitizer under the condition of this test.	Not a contact sensitizer There was no positive allergic reaction observed during the challenge phase (at 0, 24 hours and 48 hours) in animals treated with the test material and negative control	Pass
Biocompatibilty Cytotoxicity – MEM Elution	ISO 10993-5:2009	To assess cytotoxicity reactivity caused by this glove	At which level of extract concentration, the glove exhibits no cytotoxicity reactivity under the condition of this test.	Exhibit severe cytotoxicity reactivity at 100%, 50%, and 25% extract concentration. **No cytotoxicity reactivity at 12.5%, 6.25% and 3.125% extract concentrations**	Not Pass
Biocompatibilty Acute Systemic Toxicity	ISO 10993-11:2017 (E)	To demonstrate adverse effect occurring at any time within 72hours after single exposure	no adverse biological reaction under the condition of this test.	no adverse biological reaction under the condition of this test	Pass

8.0 Summary of Clinical Testing

Not applicable - Clinical data was not used to assess performance of the subject device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue) 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, Blue Colored, Powder Free Nitrile Examination Gloves, Nonsterile and tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K192954).