May 27, 2022

Encompass Industries Sdn. Bhd.
Nur Muhyiddin
QA Manager
Lot 18256, Kawasan Perindustrian Lot Q
Kertih BioPolymer Park
Kemaman, Terengganu 24300
Malaysia

Re: K220609
Trade/Device Name: Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: February 24, 2022
Received: March 2, 2022

Dear Nur Muhyiddin:

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

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)*
K220609

Device Name
Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, the glove was tested for chemotherapy drugs permeation.

The following chemotherapy drugs have been tested with the glove:

Chemotherapy Drugs	Concentration	Breakthrough Detection Time in Minutes				
		White	Blue	Black	Orange	Green
Carmustine	3.3 mg/ml	11.2	10.7	11.0	67.3	67.1
Cisplatin	1.0 mg/ml	>240	>240	>240	>240	>240
Cyclophosphamide	20.0 mg/ml	>240	>240	>240	>240	>240
Dacarbazine	10.0 mg/ml	>240	>240	>240	>240	>240
Doxorubicin HCL	2.0 mg/ml	>240	>240	>240	>240	>240
Etoposide	20.0 mg/ml	>240	>240	>240	>240	>240
Fluorouracil	50.0 mg/ml	>240	>240	>240	>240	>240
Methotrexate	25.0 mg/ml	>240	>240	>240	>240	>240
Paclitaxel	6.0 mg/ml	>240	>240	>240	>240	>240
ThioTepa	10.0 mg/ml	25.2	21.5	11.1	47.8	169.1
Mitomycin C	0.5 mg/ml	>240	>240	>240	>240	>240
Vincristine Sulfate	1.0 mg/ml	>240	>240	>240	>240	>240
Fentanyl Citrate	100 mcg/2mL	>240	>240	>240	>240	>240

*Please note that the following 2 drugs have extremely low permeation times:
1. Carmustine
2. Thiotepa

Warning: 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

K220609

Preparation date: May 27, 2022

1. Submitter

Name	:	Encompass Industries Sdn. Bhd.
Address	:	Lot 18256, Kawasan Perindustrian Lot Q, Kertih Bio-Polymer Park, 24300 Kemaman, Terengganu, Malaysia.
Telephone No.	:	+609 831 8866
Contact Person	:	Nur Atikah binti Muhammad Muhyiddin
E-mail	:	regulatory@encompass-medical.com ǀ atikah@ems-inc.com

2. Identification of Device

Trade/Proprietary Name(s)	:	1. Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for use with Chemotherapy Drugs and Fentanyl 2. Other clients' trade name and private labeling
Common Name(s)	:	Powder-Free Nitrile Examination Glove
Classification Name:	:	1. Non-powdered Patient Examination Glove (21 CFR 880.6250) 2. Patient Examination Glove, Specialty (Product Code: LZC) 3. Polymer Patient Examination Glove (Product Code: LZA)
Device Classification	:	Class I

3. Identification of Legally Marketed Device as Predicate

Predicate name	:	Black Colored, Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
510(k) number	:	K200181
Company	:	Comfort Rubber Glove Industries Sdn Bhd

4. Description of Device

The proposed Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for use with Chemotherapy Drugs and Fentanyl is a disposable device intended for over-the-counter use and is provided powder-free and non-sterile. These patient examination gloves are formulated using Nitrile. The patient examination gloves are not made with natural rubber latex. General specifications of the glove are as below:

1.	Overall Length	:	230	mm minimum
2.	Width	:	95 ± 5	mm minimum (for medium glove)
3.	Palm Thickness	:	0.05	mm minimum
4.	Finger Thickness	:	0.05	mm minimum
5.	Tensile Strength			
	a. Before Aging	:	14	MPa minimum

b. After Aging : 14 MPa minimum

6. Ultimate Elongation
   a. Before Aging : 500 % minimum
   b. After Aging : 400 % minimum
7. Pinhole AQL : 2.5

5. Intended Use / Indication for Use:

A Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for use with Chemotherapy Drugs and Fentanyl is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for chemotherapy drugs permeation test.

Table 5.1 Summary Test Results for Resistance of Powder-Free Nitrile Examination Gloves (White, Blue, Black, Orange and Green Color) to Permeation by Chemotherapy Drugs

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (minutes)				
		White	Blue	Black	Orange	Green
Carmustine (BCNU)*	3.3 mg/ml	11.2	10.7	11.0	67.3	67.1
Cisplatin	1.0 mg/mL	>240	>240	>240	>240	>240
Cyclophosphamide	20.0 mg/mL	>240	>240	>240	>240	>240
Dacarbazine	10.0 mg/mL	>240	>240	>240	>240	>240
Doxorubicin HCL	2.0 mg/mL	>240	>240	>240	>240	>240
Etoposide	20.0 mg/mL	>240	>240	>240	>240	>240
Fluorouracil	50.0 mg/mL	>240	>240	>240	>240	>240
Methotrexate	25.0 mg/mL	>240	>240	>240	>240	>240
Paclitaxel	6.0 mg/mL	>240	>240	>240	>240	>240
ThioTepa*	10.0 mg/mL	25.2	21.5	11.1	47.8	169.1
Mitomycin C	0.5 mg/mL	>240	>240	>240	>240	>240
Vincristine Sulfate	1.0 mg/mL	>240	>240	>240	>240	>240
Fentanyl Citrate	100.0 mcg/2mL	>240	>240	>240	>240	>240

*Please note that the following drugs have extremely low permeation time:
1. Carmustine (3.3 mg/mL)
2. Thiotepa (10 mg/mL)

Warning: Do not use with Carmustine and ThioTepa.

6. Comparative Technological Characteristics & Performance Information Summary

Table 6.1 Summary of Technological Characteristics Comparison between Proposed Device and Predicate Device

Character-istics	Requirement / Standard	Device Performance / Characteristic		Comparison Analysis	
		Predicate Device (K200181)	Subject Device	Comparison	Any Safety & Effective-ness Issue
Material	-	Nitrile	Nitrile	Similar	No
Color	-	Black	White Blue Black Orange Green	Minor Different (Supported by Biocompatibility Study)	No

Product Code	-	LZA LZC	LZA LZC	Similar	No
Type of Use	-	Single Use	Single Use	Similar	No
Material	-	Nitrile	Nitrile	Similar	No
Powder-Free	-	Yes	Yes	Similar	No
Sterility	-	Non-sterile	Non-Sterile	Similar	No
Intended Use / Indications for Use	-	The Black 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 purposes 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.	Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl is a disposable device intended for medical purposes that is worn on the examiner's hand, in order to prevent contamination between patient and examiner, and also prevent transmission of a wide variety of diseases to both patient and health care personnel. In addition, these gloves were tested for chemotherapy drug permeation test.	Similar	No
Dimension	ASTM D6319-10	Meets requirement	Meets requirement	Similar	No
Physical Properties	ASTM D6319-10	Meets requirement	Meets requirement	Similar	No
Freedom from Holes	ASTM D6319-10 (Tested according to ASTM D5151-06)	Meets requirements of ASTM D6319-10 (ASTM D5151)	Meets ASTM D6319-10, 21 CFR 800.20 (Tested in accordance with ASTM D5151-06)	Similar	No
Powder Residual	ASTM D6124-06	Meets requirement	Meets requirement	Similar	No
Biocompatibility	*.In Vitro* Cytotoxicity- ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic	Under the condition of study, the device extract shows potential toxicity.	Different (Supported by Acute Systemic Toxicity Study)	No
	Acute Systemic Toxicity – ISO 10993-11	-	Not an acute systemic toxic under the condition of the study.	Different (Device is proven safe to used)	No
	Skin Sensitization - ISO 10993-10	Under the condition of the study, the device is non-sensitization	Not a sensitizer under the conditions of the study.	Similar	No
	Skin Irritation - ISO 10993-10	Under the conditions of the study, the device is non-irritating	Not a primary skin irritant under the conditions of the study.	Similar	No

Table 6.2 Summary of Difference in Technological Characteristics

Characteristic	Predicate Device (K200181)	Proposed Device	Comparison Analysis	Justification
Color	Black	White Blue Black Orange Green	Minor Different (Supported by Biocompatibility Study)	Device in different color has the same non-sensitization, non-irritating and non-toxic characteristics.
Biocompatibility (In Vitro Cytotoxicity)	Meets ISO 10993:5 Under the conditions of the study, the device is non-cytotoxic	ISO 10993:5 Under the condition of study, the device extract shows potential cytotoxicity.	Different (Supported by Acute Systemic Toxicity Study)	Device has potential cytotoxic effect. Therefore, Acute Systemic Toxicity test is conducted to prove that device does not have potential toxicity.
Biocompatibility (Acute Systemic Toxicity)	-	Meets ISO 10993-11 Not an acute systemic toxic under the condition of the study.	Different (Device is proven safe to use)	Device is does not have potential toxicity effect. Therefore, similar with the predicate.

Table 6.3: Test Results for Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (ASTM D6978-05**)**

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (minutes)					
		Predicate Device (K200181)	Proposed Device				
			White	Blue	Black	Orange	Green
Carmustine (BCNU)*	3.3 mg/ml	54.1	11.2	10.7	11.0	67.3	67.1
Cisplatin	1.0 mg/mL	>240	>240	>240	>240	>240	>240
Cyclophosphamide	20.0 mg/mL	>240	>240	>240	>240	>240	>240
Dacarbazine	10.0 mg/mL	>240	>240	>240	>240	>240	>240
Doxorubicin HCL	2.0 mg/mL	>240	>240	>240	>240	>240	>240
Etoposide	20.0 mg/mL	>240	>240	>240	>240	>240	>240
Fluorouracil	50.0 mg/mL	>240	>240	>240	>240	>240	>240
Methotrexate	25.0 mg/mL	-	>240	>240	>240	>240	>240
Paclitaxel	6.0 mg/mL	>240	>240	>240	>240	>240	>240
ThioTepa*	10.0 mg/mL	1.3	25.2	21.5	11.1	47.8	169.1
Mitomycin C	0.5 mg/mL	-	>240	>240	>240	>240	>240
Vincristine Sulfate	1.0 mg/mL	-	>240	>240	>240	>240	>240
Fentanyl Citrate	100.0 mcg/2mL	>240	>240	>240	>240	>240	>240
*Warning Statement:		The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time: 1. Carmustine (3.3 mg/mL) 2. Thiotepa (10 mg/mL)	The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time: 1. Carmustine (3.3 mg/mL) 2. Thiotepa (10 mg/mL)				

7. Summary of Non-Clinical Test:

Below are the non-clinical tests that was conducted and the purposes:

Test		**Purpose**
Dimension Test	:	To evaluate whether the device meets the current ASTM D6319-19
Freedom From Hole	:	To evaluate whether the subject meets current 21 CFR 800.20, ASTM D6319-19 and test according to ASTM D5151-19
Physical Property Test	:	To evaluate whether the subjects meet current ASTM D6319-19 and test according to ASTM D412 and ASTM D573
Residual Powder Test	:	To evaluate whether the subjects meet current ASTM D6319-19 and test according to ASTM D6124-06
Biocompatibility Test (Skin Irritation)	:	To determine whether skin irritation potential of device meets ISO 10993-10.
Biocompatibility Test (Skin Sensitization)	:	To determine whether skin sensitization potential of device meets ISO 109993-10.
Biocompatibility Test (Acute Systemic Toxicity)	:	To determine whether leachable extracted from the device would cause acute systemic toxicity and meet ISO 10993-11.

Table 7.1 Summary of Dimension Test

Characteristics	**Standard**	**Size**	**Minimum Requirement**	**Device Performance (Minimum)**				
				White	**Blue**	**Black**	**Orange**	**Green**
Length	ASTM D6319-19	XS	220 mm	239 mm	235 mm	242 mm	243 mm	244 mm
		S	220 mm	236 mm	237 mm	242 mm	244 mm	241 mm
		M	230 mm	230 mm	230 mm	240 mm	245 mm	245 mm
		L	230 mm	234 mm	237 mm	255 mm	243 mm	242 mm
		XL	230 mm	232 mm	246 mm	240 mm	240 mm	245 mm
		XXL	230 mm	238 mm	238 mm	242 mm	240 mm	245 mm
Width		XS	70 ± 10 mm	75 mm	77 mm	77 mm	77 mm	77 mm
		S	80 ± 10 mm	85 mm	87 mm	86 mm	87 mm	85 mm
		M	95 ± 10 mm	93 mm	86 mm	92 mm	97 mm	97 mm
		L	110 ± 10 mm	104 mm	107 mm	104mm	108mm	107mm
		XL	120 ± 10 mm	112 mm	111 mm	114mm	118mm	117mm
		XXL	130 ± 10 mm	128 mm	128 mm	127mm	124mm	126mm
Thickness (Finger)		XS	0.05 mm	0.08mm	0.08mm	0.09 mm	0.27mm	0.25mm
		S		0.08mm	0.09mm	0.05 mm	0.27mm	0.27mm
		M		0.10mm	0.11mm	0.10 mm	0.28mm	0.27mm
		L		0.09mm	0.08mm	0.10 mm	0.27mm	0.27mm
		XL		0.07mm	0.06mm	0.10 mm	0.28mm	0.27mm
		XXL		0.07mm	0.08mm	0.07 mm	0.28mm	0.26mm
Thickness (Palm)		XS	0.05 mm	0.05mm	0.05mm	0.06 mm	0.19mm	0.19mm
		S		0.05mm	0.05mm	0.06 mm	0.19mm	0.19mm
		M		0.06mm	0.06mm	0.05 mm	0.19mm	0.18mm
		L		0.05mm	0.05mm	0.06 mm	0.22mm	0.20mm
		XL		0.05mm	0.05mm	0.06 mm	0.22mm	0.18mm
		XXL		0.05mm	0.05mm	0.06 mm	0.20mm	0.19mm

Table 7.2 Summary of Freedom of Hole Test

Characteristics	Standard	Size	Minimum Requirement	Device Performance (Minimum)				
				White	Blue	Black	Orange	Green
Freedom from Holes	A;STM D6319-19 21 CFR 800.20 (Tested as per ASTM D5151-19)	XS	AQL 2.5	Passed	Passed	Passed	Passed	Passed
		S		Passed	Passed	Passed	Passed	Passed
		M		Passed	Passed	Passed	Passed	Passed
		L		Passed	Passed	Passed	Passed	Passed
		XL		Passed	Passed	Passed	Passed	Passed
		XXL		Passed	Passed	Passed	Passed	Passed

Table 7.3 Summary of Physical Property Test

Characteristics	Standard	Size	Minimum Requirement	Device Performance (Minimum)				
				White	Blue	Black	Orange	Green
Before Aging (Tensile [MPa])	ASTM D6319-19 (Tested as per ASTM D412-16)	XS	14 MPa	23.2	21.0	21.3	20.7	21.1
		S		21.2	24.5	23.6	20.0	20.1
		M		22.8	21.6	22.3	21.0	28.8
		L		20.7	23.7	21.6	21.4	20.9
		XL		20.5	20.2	24.3	20.9	22.0
		XXL		22.8	23.6	22.2	23.0	22.1
Before Aging (Elongation [%])		XS	500 %	528	520	515	527	533
		S		527	549	518	515	556
		M		520	522	530	549	548
		L		528	521	527	531	523
		XL		536	521	528	533	524
		XXL		526	524	528	525	525
After Aging (Tensile [MPa])		XS	14 MPa	23.0	20.2	23.0	24.5	21.4
		S		20.2	24.6	26.6	22.7	20.4
		M		26.8	19.8	22.7	22.2	26.4
		L		24.9	26.1	21.4	25.2	21.7
		XL		26.3	23.1	28.8	22.2	24.6
		XXL		23.3	21.0	20.0	27.4	20.1
After Aging (Elongation [%])		XS	400 %	432	461	414	430	465
		S		427	466	421	412	446
		M		444	457	425	466	440
		L		488	423	436	447	455
		XL		458	424	434	432	431
		XXL		437	435	433	425	425

Table 7.4 Summary of Residual Powder Test

Characteristics	Standard	Size	Minimum Requirement	Device Performance (Minimum)				
				White	Blue	Black	Orange	Green
Residual Powder (mg)	ASTM D6319-19 (Tested as per ASTM D6124-06)	XS	≤ 2.0 mg of residual powder per glove	0.98	0.68	0.80	0.82	0.96
		S		0.86	0.72	0.86	0.98	0.82
		M		0.92	0.88	0.94	0.92	0.92
		L		0.78	0.76	0.92	0.78	0.90
		XL		0.84	0.98	0.84	0.68	0.86
		XXL		0.74	0.82	0.92	0.84	0.98

Table 7.5 Summary of Biocompatibility Test

Characteristics	Standard	Minimum Requirement	Device Performance				
			White	Blue	Black	Orange	Green
Skin Irritation	ISO 10993-10	N/A	Non-irritant under the conditions of the study.				
Skin Sensitization		N/A	Non-sensitizer under the conditions of the study.				
Acute Systemic Toxicity	ISO 10993-11	N/A	Not an acute systemic toxic under the condition of the study.				

8. Summary of Clinical Test:

Clinical data is not required.

9. Conclusion:

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