July 8, 2025

Encompass Industries Sdn. Bhd.
Atikah Muhyiddin
QA Manager
Lot 18256, Kawasan Perindustrian Lot Q,
Kertih Bio-Polymer Park
Kemaman, Terengganu 24300
Malaysia

Re: K250342
Trade/Device Name: Powder-Free Polychloroprene Examination Glove (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, OPJ, QDO, OPC
Dated: June 12, 2025
Received: June 12, 2025

Dear Atikah 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250342

Device Name
Powder-Free Polychloroprene Examination Glove (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 examiner's hand to prevent contamination between patient and examiner. In addition, the glove was evaluated using ASTM D6978 for permeation of chemotherapy drugs and fentanyl citrate. The glove is single use and non-sterile.

The following chemotherapy drugs have been tested on the glove:

Chemotherapy Drugs	Concentration	Breakthrough Detection Time
Carmustine*	3.3 mg/mL	23.2 min
Cisplatin	1.0 mg/mL	>240 min
Cyclophosphamide	20.0 mg/mL	>240 min
Dacarbazine	10.0 mg/mL	>240 min
Doxorubicin HCL	2.0 mg/mL	>240 min
Etoposide	20.0 mg/mL	>240 min
Fluorouracil	50.0 mg/mL	>240 min
Methotrexate	25.0 mg/mL	>240 min
Paclitaxel	6.0 mg/mL	>240 min
ThioTepa*	10.0 mg/mL	13.5 min
Mitomycin C	0.5 mg/mL	>240 min
Vincristine Sulfate	1.0 mg/mL	>240 min
Fentanyl		
Fentanyl Citrate	100.0 mcg/2mL	>240 min

*Please note that the following drugs have low permeation time.
1. Carmustine
2. ThioTepa

Warning: Do not use with Carmustine & 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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K250342

510(k) Summary

Preparation Date: July 3, 2025

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	:	Atikah Muhyiddin
E-mail	:	regulatory@encompass-medical.com | atikah@ems-inc.com

2. Identification of Device

Trade/Proprietary Name(s)	:	Powder-Free Polychloroprene Examination Glove (Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl
Common Name(s)	:	Powder-Free Polychloroprene Examination Glove
Classification Name:	:	1. Non-powdered Patient Examination Glove (21 CFR 880.6250) 2. Polymer Patient Examination Glove (Product Code: LZA) 3. Patient Examination Glove, Specialty (Product Code: LZC) 4. Glove with Labelling Claims for Use with Chemotherapy Drugs (OPJ) 5. Fentanyl and Other Opioid Protective Glove (QDO) 6. Powder-Free Polychloroprene Patient Examination Glove (OPC)
Device Classification	:	Class I

3. Identification of Legally Marketed Device as Predicate and Reference Device

Predicate Device	:	Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs
510(k) number	:	K212148
Company	:	Ansell Healthcare Products LLC
Reference Device	:	Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl
510(k) number	:	K220609
Company	:	Encompass Industries Sdn. Bhd.

4. Description of Device

The proposed Powder-Free Polychloroprene Examination Glove (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 Polychloroprene. The gloves are not made with natural rubber latex. General specifications of the glove are as below:

1.	Overall Length	:	240	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.	Cuff Thickness	:	0.05	mm minimum
6.	Tensile Strength			
	a. Before Aging	:	14	MPa minimum
	b. After Aging	:	14	MPa minimum
7.	Ultimate Elongation			
	a. Before Aging	:	500	% minimum
	b. After Aging	:	400	% minimum
8.	Pinhole AQL	:	2.5	

5. Intended Use / Indication for Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on examiner's hand to prevent contamination between patient and examiner. In addition, the glove was evaluated using ASTM D6978 for permeation of chemotherapy drugs and fentanyl citrate. The glove is single use and non-sterile.

The following chemotherapy drugs have been tested on the glove:

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU)*	3.3 mg/ml	23.2 min
Cisplatin	1.0 mg/ml	>240 min
Cyclophosphamide	20.0 mg/ml	>240 min
Dacarbazine	10.0 mg/ml	>240 min
Doxorubicin HCL	2.0 mg/ml	>240 min
Etoposide	20.0 mg/ml	>240 min
Fluorouracil	50.0 mg/ml	>240 min
Methotrexate	25.0 mg/ml	>240 min
Paclitaxel	6.0 mg/ml	>240 min
ThioTepa*	10.0 mg/ml	13.5 min
Mitomycin C	0.5 mg/ml	>240 min
Vincristine Sulfate	1.0 mg/ml	>240 min
*Warning Statement:	Please note that the following drugs have extremely low permeation time: 1. Carmustine (3.3 mg/ml) 2. ThioTepa (10.0 mg/ml)	

Fentanyl	Concentration	Minimum Breakthrough Detection Time (minutes)
Fentanyl Citrate	100 mcg/2mL	>240 min

6. Comparative Technological Characteristics & Performance Information Summary

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

Characteristic	Device Performance / Characteristic			Comparison Analysis	
	Predicate Device (K212148)	**Reference Device (K220609)**	**Proposed Device (K250342)**	**Compari-son**	**Any Safety & Effectiveness Issue**
Glove Name	Non-Sterile Powder-Free Polychloroprene Examination Glove (Blue) Tested for Use with Chemotherapy Drugs	Powder-Free Nitrile Examination Glove (White, Blue, Black, Orange and Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl	Powder-Free Polychloroprene Examination Glove (Green Color) Tested for Use with Chemotherapy Drugs and Fentanyl	Similar	No
Material	Polychloroprene	Nitrile	Polychloroprene	Similar to predicate	No
Color	Blue	White, Blue, Black, Orange, Green	Green	Minor Difference	No
Size	XS, S, M, L, XL	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	Similar	No
Device Classification Regulation	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Similar	No
Product Code	LZA, LZC	LZA, LZC	LZA, LZC, OPJ, QDO, OPC	Similar	No
Type of Use	Single Use	Single Use	Single Use	Similar	No
Rx / OTC	OTC	OTC	OTC	Similar	No
Powder-Free	Yes	Yes	Yes	Similar	No
Sterility	Non-sterile	Non-sterile	Non-Sterile	Similar	No
Intended Use / Indication for Use	A powder-free patient examination glove is a disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	A disposable device intended for medical purposes that is worn on the examiner's hand, in order to prevent contamination between patient and examiner. This device is for over-the-counter use and is for single use only. In addition, these gloves were tested chemotherapy drug permeation test.	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on examiner's hand to prevent contamination between patient and examiner. In addition, the glove was evaluated using ASTM D6978 for permeation of chemotherapy drugs and fentanyl citrate. The glove is single use and non-sterile.	Similar	No
Dimension	Meets requirement of ASTM D6977-19	Meets requirement of ASTM D6319-19	Meets requirement of ASTM D6977-19	Similar	No
Physical Properties	Meets requirement of ASTM D6977-19	Meets requirement of ASTM D6319-19	Meets requirement of ASTM D6977-19	Similar	No

Freedom from Holes	Meets requirement of ASTM D6977-19	Meets requirement of ASTM D6319-19 and 21 CFR 800.20)	Meets requirement of ASTM D6977-19 and 21 CFR 800.20)	Similar[1]	No
Powder Residual	Meets requirement of ASTM D6977-19	Meets requirement of ASTM D6319-19	Meets requirement of ASTM D6977-19	Similar	No
Biocompa-tibility	ISO 10993-10 Skin Irritation Under the conditions of the study, not an irritant	ISO 10993-10 Skin Irritation Not a primary skin irritant under the conditions of the study.	ISO 10993-10 Skin Irritation The test article was not considered as an irritant.	Similar	No
	ISO 10993-10 Skin Sensitization Under the conditions of the study, not a sensitizer	ISO 10993-10 Skin Sensitization Not a sensitizer under the conditions of the study.	ISO 10993-10 Skin Sensitization The test article was not considered a sensitizer.	Similar	No
	ISO 10993-5.*In Vitro* Cytotoxicity Under the conditions of the study undiluted, 1:2, and 1:4 dilutions were cytotoxic (grade 4). Dilutions of 1:8 (grade 2), 1:16 (grade 1), 1:32 and 1:64 (grade 0) were noncytotoxic.	ISO 10993-5.*In Vitro* Cytotoxicity Under the condition of study, the device extract shows potential toxicity.	ISO 10993-5.*In Vitro* Cytotoxicity The test extract showed evidence of toxicity.	Similar	No
	ISO 10993-11 Acute Systemic Toxicity Under the conditions of the study, no evidence of systemic toxicity	ISO 10993-11 Acute Systemic Toxicity Not an acute systemic toxic under the condition of the study.	ISO 10993-11 Acute Systemic Toxicity There was no evidence of acute systemic toxicity.	Similar	No

[1]*Device performance demonstrates that the proposed device meets 21 CFR 800.20 as the tested samples show results below the rejection number at 2.5 AQL for patient examination glove, thus meet the requirement of ASTM D6977-19 which is Inspection G-1, AQL 2.5. Similar to predicate device.*

Table 6.2 Summary of Difference in Technological Characteristics

Characteristic	**Predicate Device (K212148)**	**Reference Device (K220609)**	**Proposed Device (K250342)**	**Comparison Analysis**	**Justification**
Color	Blue	White, Blue, Black, Orange, Green	Green	Different (Supported by Biocompatibility Study and Performance Testing)	Devices in different colors have the same non-sensitization, non-irritating and non-toxic characteristics and meet the same performance specifications.

Table 6.3: Test Results for Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (ASTM D6978-05) Comparison between Proposed, Reference and Predicate Device

Chemotherapy Drugs & Concentration	Minimum Breakthrough Detection Time (minutes)							Comparison
	Predicate Device (K212148)	Reference Device (K220609)					Proposed Device (K250342)	
		White	Blue	Black	Orange	Green		
Carmustine (3.3 mg/ml)	45.4	11.2	10.7	11.0	67.3	67.1	23.2	Similar
Cisplatin (1.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Cyclophosphamide(20.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Dacarbazine (10.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Doxorubicin HCL (2.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Etoposide (20.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Fluorouracil (50.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Methotrexate (25.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
Paclitaxel (6.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar
ThioTepa (10.0 mg/mL)	23.5	25.2	21.5	11.1	47.8	169.1	13.5	Similar
Mitomycin C (0.5 mg/mL)	-	>240	>240	>240	>240	>240	>240	Similar to K220609 [2]
Vincristine Sulfate (1.0 mg/mL)	>240	>240	>240	>240	>240	>240	>240	Similar

Fentanyl & Concentration	Minimum Breakthrough Detection Time (minutes)							Comparison
	Predicate Device (K212148)	Reference Device (K220609)					Proposed Device (K250342)	
		White	Blue	Black	Orange	Green		
Fentanyl Citrate (100mcg/2mL)	-	>240	>240	>240	>240	>240	>240	Similar to K220609 [2]

[2]*Chemotherapy and fentanyl drug names and its minimum breakthrough detection time of the proposed device will be listed on the packaging. Therefore, the differences do not raise concerns about safety, effectiveness and substantial equivalence of the proposed device compared to the predicate.*

7. Summary of Non-Clinical Test:

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

Test		Purpose
Dimension Test	:	To evaluate whether the device meets the current ASTM D6977-19
Freedom From Hole	:	To evaluate whether the subject meets current 21 CFR 800.20, ASTM D6977-19 and test according to ASTM D5151-19
Physical Property Test	:	To evaluate whether the subjects meet current ASTM D6977-19 and test according to ASTM D412 and ASTM D573
Residual Powder Test	:	To evaluate whether the subjects meet current ASTM D6977-19 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	Requirement	Device Performance
Length	ASTM D69779-19	XS	≥ 220 mm	≥ 251 mm
		S	≥ 220 mm	≥ 250 mm
		M	≥ 230 mm	≥ 251 mm
		L	≥ 230 mm	≥ 248 mm
		XL	≥ 230 mm	≥ 250 mm
		XXL	≥ 230 mm	≥ 250 mm
Width		XS	70 ± 10 mm	79 - 80 mm
		S	80 ± 10 mm	86 - 88 mm
		M	95 ± 10 mm	98 - 100 mm
		L	110 ± 10 mm	111 - 113 mm
		XL	120 ± 10 mm	115 - 118 mm
		XXL	130 ± 10 mm	127 - 129 mm
Thickness (Finger)		XS	≥ 0.05 mm	≥ 0.11 mm
		S		≥ 0.11 mm
		M		≥ 0.11 mm
		L		≥ 0.11 mm
		XL		≥ 0.11 mm
		XXL		≥ 0.11 mm
Thickness (Palm)		XS	≥ 0.05 mm	≥ 0.08 mm
		S		≥ 0.08 mm
		M		≥ 0.08 mm
		L		≥ 0.08 mm
		XL		≥ 0.08 mm
		XXL		≥ 0.09 mm
Thickness (Cuff)		XS	≥ 0.05 mm	≥ 0.06 mm
		S		≥ 0.07 mm
		M		≥ 0.07 mm
		L		≥ 0.07 mm
		XL		≥ 0.07 mm
		XXL		≥ 0.07 mm

Table 7.2 Summary of Freedom of Hole Test

Characteristics	Standard	Size	Requirement	Device Performance[3]
Freedom from Holes	ASTM D6977-19 21 CFR 800.20 (Tested according to ASTM D5151-19)	XS	AQL 2.5	Passed
		S		Passed
		M		Passed
		L		Passed
		XL		Passed
		XXL		Passed

[3]Device performance demonstrates that the proposed device meets 21 CFR 800.20 as the tested samples show results below the rejection number at 2.5 AQL for patient examination glove, thus meet the requirement of ASTM D6977-19 which is Inspection G-1, AQL 2.5. Similar to predicate device.

Table 7.3 Summary of Physical Property Test

Characteristics	Standard	Size	Minimum Requirement	Device Performance
Before Aging (Tensile [MPa])	ASTM D6977-19 (Tested as per ASTM D412-16 and ASTM D573)	XS	14 MPa	23.9
		S		21.7
		M		33.4
		L		28.9
		XL		27.5
		XXL		16.83
Before Aging (Elongation [%])		XS	500 %	521
		S		551
		M		596
		L		554
		XL		591
		XXL		556
After Aging (Tensile [MPa])		XS	14 MPa	30.4
		S		33.0
		M		40.2
		L		23.8
		XL		26.2
		XXL		29.9
After Aging (Elongation [%])		XS	400 %	448
		S		428
		M		462
		L		438
		XL		453
		XXL		461

Table 7.4 Summary of Residual Powder Test

Characteristics	Standard	Size	Requirement	Device Performance[4]
Residual Powder (mg)	ASTM D6977-19 ASTM D6124-06	XS	≤ 2.0 mg of residual powder per glove	0.30 mg/glove
		S		0.32 mg/glove
		M		0.24 mg/glove
		L		0.26 mg/glove
		XL		0.22 mg/glove
		XXL		0.30 mg/glove

[4]Device Performance shows the residual powder content of each glove size, which meets ASTM D6977-19 and ASTM D6124-06 (2017) requirements for Powder Free Gloves; ≤ 2 mg per glove. Similar to predicate device.

Table 7.5 Summary of Biocompatibility Test

Characteristics	Standard	Requirement	Device Performance
Skin Irritation	ISO 10993-10	Score ≤ 0.4	The test article was not considered as an irritant.
Skin Sensitization	ISO 10993-10	Score < 1	The test article was not considered a sensitizer.
Acute Systemic Toxicity	ISO 10993-11	No significant biological reactivity	There was no evidence of acute systemic toxicity.

8. Summary of Clinical Test:

Clinical data is not required.

9. Conclusion:

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