January 27, 2023

Semperit Investments Asia PTE. LTD.
℅ Jay Mansour
Regulatory Consultant / Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K223903
Trade/Device Name: Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl SMALL SIZE (NGPF102); MEDIUM SIZE (NGPF103); LARGE SIZE (NGPF104); X-LARGE SIZE (NGPF105)
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: December 27, 2022
Received: December 28, 2022

Dear Jay Mansour:

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,

Allan Guan -S

For 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)*
K223903

Device Name
Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl
SMALL SIZE (NGPF102); MEDIUM SIZE (NGPF103); LARGE SIZE (NGPF104); X-LARGE SIZE

Indications for Use *(Describe)*
This device is an ambidextrous patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between patient and examiner.
The tested chemotherapy drugs are:
Carmustine (BCNU) (3.3 mg/ml). Permeation time: Carmustine (BCNU) has extremely low permeation times of 14.7 minutes.
Cisplatin (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Cyclophosphamide (Cytoxan) (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Cytarabine (100 mg/ml). Permeation time: no breakthrough up to 240 minutes
Dacarbazine (DTIC) (10.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Etoposide (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Fluorouracil (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
lfosfamide (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Methotrexate (25.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Mitomycin C (0.5 mg/ml). Permeation time: no breakthrough up to 240 minutes
Mitoxantrone (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Thiotepa (10.0 mg/ml). Permeation time: Thiotepa has extremely low permeation times of 13.6 minutes
Vincristine Sulfate (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
The tested Opioid is:
Fentanyl Citrate Injection (100mcg/2mL). Permeation: no breakthrough up to 240 minutes

Please note that the following drugs have extremely low permeation times:
Carmustine: 14.7 minutes
Thiotepa: 13.6 minutes

Warning: DO NOT USE WITH CARMUSTINE OR 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223903- 510(k) summary

I Submitter

Device submitter: SEMPERIT INVESTMENTS ASIA PTE. LTD.
8 Jurong Town Hall Road, #29-03 To 06 The JTC Summit
Singapore 609434

Contact person: Jay Mansour
Mansour Consulting LLC
Regulatory consultant
Phone (678) 908-8180
Email jay@mansourconsulting.com

Date of preparation: January 27, 2023

II Proposed device

510(k) Number: K223903
Trade/Device Name: Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl
SMALL SIZE (NGPF102); MEDIUM SIZE (NGPF103); LARGE SIZE (NGPF104); X-LARGE SIZE (NGPF105)
Regulation number: 21 CFR 880.6250
Regulation name: Non-powdered Patient Examination Glove
Regulatory class: Class I
Product code: LZA (primary), LZC, OPJ, QDO
Review panel: General Hospital

III Predicate devices

510(k) Number: K171378
Trade/Device name: Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs
Regulation number: 21 CFR 880.6250
Regulation name: Non-powdered Patient Examination Glove
Regulatory class: Class I

Product code: LZA (primary), LZC
Manufacturer: SEMPERIT INVESTMENTS ASIA PTE. LTD.

IV Device description

The Non-Sterile, Single use, Powder-free Examination glove, Blue, tested for use with Chemotherapy Drugs and fentanyl is provided in blue. It meets all the requirements of ASTM D6319. It is a 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 were tested for use with chemotherapy drugs as well as Fentanyl, per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drug. It can be available in 4 specifications: S, M, L and XL.

V Indications for use

This device is an ambidextrous patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between patient and examiner.
The tested chemotherapy drugs are:
Carmustine (BCNU) (3.3 mg/ml). Permeation time: Carmustine (BCNU) has extremely low permeation times of 14.7 minutes.
Cisplatin (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Cyclophosphamide (Cytoxan) (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Cytarabine (100 mg/ml). Permeation time: no breakthrough up to 240 minutes
Dacarbazine (DTIC) (10.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Etoposide (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Fluorouracil (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Methotrexate (25.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Mitomycin C (0.5 mg/ml). Permeation time: no breakthrough up to 240 minutes
Mitoxantrone (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
Thiotepa (10.0 mg/ml). Permeation time: Thiotepa has extremely low permeation times of 13.6 minutes
Vincristine Sulfate (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes
The tested Opioid is:
Fentanyl Citrate Injection (100mcg/2mL). Permeation: no breakthrough up to 240 minutes

Please note that the following drugs have extremely low permeation times:
Carmustine: 14.7 minutes
Thiotepa: 13.6 minutes
Warning: DO NOT USE WITH CARMUSTINE OR THIOTEPA

VI Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

➢ ASTM D5151 Standard Test Method for Detection of Holes in Medical Gloves

➢ ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves

➢ ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application

➢ ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

➢ ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

Table 1 Summary of Non-Clinical Performance Testing

Test method	Purpose	Acceptance Criteria			Result
ASTM D6319	Dimensions	Extra-Small	Length：≥220mm; Width: 70±10 mm		Pass
		Small	Length：≥220mm; Width: 80±10mm		
		Medium	Length：≥230mm; Width: 95±10mm		
		Large	Length：≥230mm; Width: 110±10mm		
		Extra- Large	Length：≥230mm; Width: 120±10mm		
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Pass
	Physical properties	Before Aging	Tensile Strength	≥14MPa	Pass
			Ultimate Elongation	≥500%	
		After Aging	Tensile Strength	≥14MPa	Pass
			Ultimate Elongation	≥400%	
ASTM D5151	Freedom from holes	Shall comply with freedom from holes (AQL = 2.5) when tested in accordance with ASTM D5151.			Pass
ASTM D6124	Powder-free Residue	Have a powder residue limit of 2.0 mg in accordance with ASTM D6124.			Pass
ISO 10993-10	To determine if the finished device material is an irritant.	Non-irritating			Under the conditions of the study not an irritant/ Pass
ISO 10993-10	To determine if the finished device material is a sensitizer.	Non-sensitizing			Under conditions of the study, not a sensitizer. / Pass
ASTM D6978	Resistance to permeation by Fentanyl	No breakthrough when tested for permeation with Fentanyl in accordance with ASTM D6978.			Pass
	Resistance to Permeation by Chemotherapy Drugs	Covered in predicate device 510(k) K171378 for Carmustine (BCNU) (3.3 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (Cytoxan) (20.0 mg/ml) Cytarabine (100 mg/ml) Dacarbazine (DTIC) (10.0 mg/ml) Doxorubicin Hydrochloride (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Ifosfamide (50.0 mg/ml) Methotrexate (25.0 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0 mg/ml) Paclitaxel (Taxol) (6.0 mg/ml)			Pass

		Vincristine Sulfate (1.0 mg/ml) Thiotepa (10.0 mg/ml)	

VII Clinical Test Conclusion

No clinical study is included in this submission.

VIII Summary of Technological characteristics

	Subject device	Predicate device	Comments
Manufacturer	SEMPERIT INVESTMENTS ASIA PTE. LTD.	SEMPERIT INVESTMENTS ASIA PTE. LTD.	N/A
510(k) number	TBD	K171378	N/A
Device trade or proprietary name	Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and fentanyl	Non-Sterile, Powder-free Examination glove, Blue, tested for use with Chemotherapy Drugs	Different: except the addition of Fentanyl for subject device, it is identical
Device Classification Name/ Regulation number	Patient Examination Glove 21 CFR Part 880.6250	Patient Examination Glove 21 CFR Part 880.6250	Identical
Product Code	LZA (primary), LZC, OPJ, QDO	LZA (primary), LZC	Different: added two product codes

Indications for use	. This device is an ambidextrous patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are: Carmustine (BCNU) (3.3 mg/ml). Permeation time: Carmustine (BCNU) has extremely low permeation times of 14.7 minutes. Cisplatin (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Cyclophosphamide (Cytoxan) (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Cytarabine (100 mg/ml). Permeation time: no breakthrough up to 240 minutes Dacarbazine (DTIC) (10.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Doxorubicin Hydrochloride (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Etoposide (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Fluorouracil (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Ifosfamide (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Methotrexate (25.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitomycin C (0.5 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitoxantrone (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Paclitaxel (Taxol) (6.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Thiotepa (10.0 mg/ml). Permeation time: Thiotepa has extremely low permeation times of 13.6 minutes Vincristine Sulfate (1.0 mg/ml). Permeation time: no Breakthrough up to 240 minutes. The tested Opiod is: Fentanyl Citrate Injection (100mcg/2mL). Permeation: no breakthrough up to 240 minutes Please note that the following drugs have extremely low permeation times: Carmustine: 14.7 minutes Thiotepa: 13.6 minutes Warning: DO NOT USE WITH CARMUSTINE OR THIOTEPA	This device is an ambidextrous patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are: Carmustine (BCNU) (3.3 mg/ml). Permeation time: Carmustine (BCNU) has extremely low permeation times of 14.7 minutes. Cisplatin (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Cyclophosphamide (Cytoxan) (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Cytarabine (100 mg/ml). Permeation time: no breakthrough up to 240 minutes Dacarbazine (DTIC) (10.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Doxorubicin Hydrochloride (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Etoposide (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Fluorouracil (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Ifosfamide (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Methotrexate (25.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitomycin C (0.5 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitoxantrone (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Paclitaxel (Taxol) (6.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Thiotepa (10.0 mg/ml). Permeation time: Thiotepa has extremely low permeation times of 13.6 minutes Vincristine Sulfate (1.0 mg/ml). Permeation time: no Breakthrough up to 240 minutes. DO NOT USE WITH CARMUSTINE OR THIOTEPA	Different Subject device includes Fentanyl, while predicate device does not. Other than for Fentanyl, the indications for use are identical. Note: Adding the Fentanyl to the indication does not affect the intended use. The device's intended use is it would be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants. Therefore, there are no differences to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and therefore the change in the indication for use (by adding Fentanyl) does not affect the safety and effectiveness of the device when used as labeled.
Materials	Nitrile	Nitrile	Identical
Color	Blue	Blue	Identical

Standards used	1. ISO 10993-10 2. ASTM D6319-19 3. ASTM D6124-06 (reapproved 2017) 4. ASTM D5151-19 5. ASTM D6978-05 (reapproved 2019) 6. ISO 2859-1 7. ASTM D412-16e1 8. ASTM D3767-03 (2020) 9. ASTM D573-04 (2019)	1. ISO 10993-10 2. ASTM D6319-10 (reapproved 21015) 3. ASTM D6124-06 (2011) 4. ASTM D5151-06 5. ASTM D6978-05 (re-approved 2013) 6. ISO 2859-1 7. ASTM D412-16 8. ASTM D3767-03 (2014) 9. ASTM D573-04 (2015)	Identical, with justification provided below, following the same numbering sequence: 1. See biocompatibility below 2. The changes did not affect product design, production and compliance (1st change: section 1.5. 2nd change: adding calculation options instead of actual cutting. 3rd change: limitation on accelerated aging option based on natural aging. 4th change: size XXL is introduced in the revised standard BUT it is NOT added in this submission). Recognition number is updated from 6-244 to 6-446 3. No changes in the standard. Recognition number 6-178 remains the same. 4. The changes did not affect product design, production and compliance (1st change: section 1.7. 2nd change: temperature of the water leak test). Recognition number is updated from 6-175 to 6-424 5. No change in the standard. Recognition number 6-147 remains the same 6. No change in the standard. Recognition number was updated from 5-62 to 5-88 7. No changes in the standard. Version D412-16 was accepted in 510k submissions without recognition number. D412-16e1 is now recognized under recognition number 8-559. 8. No changes in the standard. Standard accepted in 510k submissions but still not having a recognition number. 9. No changes in the standard. Standard accepted in 510kk submissions but still not having a recognition number.
Non-Sterile, Single Use, disposable	Yes	Yes	Identical
Packaging	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Identical
Labeling Features	Non-Sterile Powder Free Examination Gloves Ambidextrous, by Size Single use only Device Color Manufactured for: Lot Number: Quantity by Weight Made in Malaysia	Non-Sterile Powder Free Examination Gloves Ambidextrous, by Size Single use only Device Color Manufactured for: Lot Number: Quantity by Weight Made in Malaysia	Identical
Labeling Claim	Tested for Use with Chemotherapy Drugs and Fentanyl	Tested for Use with Chemotherapy Drugs	Identical except for the addition of Fentanyl, which is the subject of this submission

Biocompatibility	Sensitization and irritation compliant as per ISO 10993-10	Sensitization and irritation compliant as per ISO 10993-10	Identical based on recognition number 2-174 covering sensitization and irritation in the same standard

IX Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission K223903, Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs , cleared under 510(k) K171378.