October 4, 2019

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

Re: K183441
Trade/Device Name: Powder-free Nitrile Patient Examination Glove, Green Colored, Non-sterile, Low Dermatitis Potential, and 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, LZC
Dated: August 29, 2019
Received: September 3, 2019

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183441

Device Name
Powder-free Nitrile Patient Examination Glove, Green Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
This device is an ambidextrous patient examination glove that is non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs listed below

	Minimum Breakthrough detection time (minutes)
Carmustine (BCNU) (3.3 mg/ml)	15.9
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine (100mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	11.1
Vincristine Sulfate (1.0 mg/ml)	>240

Do not use with Carmustine and Thiotepa.
Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 15.9 minutes and Thiotepa:11.1 minutes.

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.

510(k) # K183441

510k Summary

As required by 21 CFR 807.92

1- Date summary prepared: September 26, 2019

2- Owner/Submitter/Sponsor/Applicant information:

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

Contact person
Name: Jay Mansour, MSQA, BE, RAC
Title: regulatory consultant- Mansour Consulting LLC – Principal
Phone: (678) 908-8180
Email address: jay@mansourconsulting.com

3- Device information:

Common/usual/classification name:

Powder-Free Nitrile Patient Examination Glove

Device name:

Powder-free Nitrile Patient Examination Glove, Green colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs

FDA 3 letter code	LZA, LZC
FDA regulation number: 21 CFR	880.6250
Regulation medical specialty	General Hospital
Review panel	General Hospital
Class	I

4- Predicate device:

510k number	Trade or Proprietary or Model Name	Manufacturer
K151824	--Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, and Tested for use with Chemotherapy Drugs --Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and Tested for use with Chemotherapy Drugs	KOSSAN INTERNATIONAL SDN. BHD.

5- Description of the device:

The Powder-free Nitrile Patient Examination Glove, Green Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs meets all the requirements of ASTM standard D6319-10. It is an ambidextrous medical glove, which is a disposable device, provided in x-small, small, medium, large and x-large sizes. In addition, these gloves were tested for use with chemotherapy drugs per ASTM D6978-05 "*Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drug*," and Modified-Draize-95 Test, per FDA guidance document "*Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products*," 1999.

6- Indications for use

This device is an ambidextrous patient examination glove that is non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs listed below

	Minimum Breakthrough detection time (minutes)
Carmustine (BCNU) (3.3 mg/ml)	15.9
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine (100mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	11.1
Vincristine Sulfate (1.0 mg/ml)	>240

Do not use with Carmustine and Thiotepa.

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 15.9 minutes and Thiotepa:11.1 minutes.

7- Technological Characteristics:

Shown below is the technological characteristics comparison of the subject device and the predicate device.

	Subject device	Predicate Device	Comments
Manufacturer	SEMPERIT INVESTMENTS ASIA PTE. LTD.	KOSSAN INTERNATIONAL SDN. BHD.	N/A
510(k) number	K183441	K151824	N/A
Device trade or proprietary name	Powder-free Nitrile Patient Examination Glove, Green Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs	Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, and Tested for use with Chemotherapy Drugs Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and Tested for use with Chemotherapy Drugs	Identical, except that subject device is in green, while predicate device is in blue or white.
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, LZC	LZA, LZC	Identical
Intended 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 to prevent contamination between patient and examiner. The tested chemotherapy drugs are:	A 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. The tested chemotherapy drugs are:	Identical, except for lower breakthrough time for Thiotepa. (Both devices are ambidextrous)

CARMUSTINE (BCNU) 3.3 MG/ML	extremely low permeation times of 15.9 minutes.
CISPLATIN 1.0 MG/ML	no breakthrough up to 240 minutes
CYCLOPHOSPHAMIDE (CYTOXAN) 20.0 MG/ML	no breakthrough up to 240 minutes
CYTARABINE 100 MG/ML	no breakthrough up to 240 minutes
DACARBAZINE (DTIC) 10.0 MG/ML	no breakthrough up to 240 minutes
DOXORUBICIN HYDROCHLORIDE 2.0 MG/ML	no breakthrough up to 240 minutes

CARMUSTINE (BCNU) 3.3 MG/ML	extremely low permeation times of 10.4 minutes.
CISPLATIN 1.0 MG/ML	no breakthrough up to 240 minutes
CYCLOPHOSPHAMIDE (CYTOXAN) 20.0 MG/ML	no breakthrough up to 240 minutes
CYTARABINE 100 MG/ML	no breakthrough up to 240 minutes
DACARBAZINE (DTIC) 10.0 MG/ML	no breakthrough up to 240 minutes
DOXORUBICIN HYDROCHLORIDE 2.0 MG/ML	no breakthrough up to 240 minutes

	ETOPOSIDE 20.0 MG/ML	no breakthrough up to 240 minutes		**ETOPOSIDE 20.0 MG/ML**	no breakthrough up to 240 minutes	
	FLUOROURACIL 50.0 MG/ML	no breakthrough up to 240 minutes		**FLUOROURACIL 50.0 MG/ML**	no breakthrough up to 240 minutes	
	IFOSFAMIDE 50.0 MG/ML	no breakthrough up to 240 minutes		**IFOSFAMIDE 50.0 MG/ML**	no breakthrough up to 240 minutes	
	METHOTREXATE 25.0 MG/ML	no breakthrough up to 240 minutes		**METHOTREXATE 25.0 MG/ML**	no breakthrough up to 240 minutes	
	MITOMYCIN C 0.5 MG/ML	no breakthrough up to 240 minutes		**MITOMYCIN C 0.5 MG/ML**	no breakthrough up to 240 minutes	
	MITOXANTRONE 2.0 MG/ML	no breakthrough up to 240 minutes		**MITOXANTRONE 2.0 MG/ML**	no breakthrough up to 240 minutes	
	PACLITAXEL (TAXOL) 6.0 MG/ML	no breakthrough up to 240 minutes		**PACLITAXEL (TAXOL) 6.0 MG/ML**	no breakthrough up to 240 minutes	
	THIOTEPA 10.0 MG/ML	extremely low permeation times of 11.1 minutes		**THIOTEPA 10.0 MG/ML**	breakthrough after 90.5 minutes	
	VINCRISTINE SULFATE 1.0 MG/ML	no breakthrough up to 240 minutes		**VINCRISTINE SULFATE 1.0 MG/ML**	no breakthrough up to 240 minutes	
Materials	Nitrile			Nitrile		Identical
Color	Green			Blue or White		- Similar (green versus blue)
Standards used	ASTM D6319-10 ASTM D5151-06 ASTM D6124-06 ASTM D6978-05(2013) ASTM D412-16 ASTM D3767-03 ANSI/AAMI/ISO 10993-5 ISO 10993-10 ISO 2859-1			ASTM D6319-10 ASTM D5151-11 ASTM D6124-11 ASTM D6978-05 (Reapproved 2013) ISO 10993-10		Identical Note: ASTM D412-16, D3767-03 and ISO 2859-1 are supporting standards
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 by: Lot Number: Quantity by Weight Made in Malaysia			Non-Sterile Powder Free Examination Gloves Ambidextrous, by Size Single use only Device Color Manufactured by: Lot Number: Quantity by Weight Made in Malaysia		Identical
Sizes	X-Small, Small, Medium, Large, X-Large			X-Small, Small, Medium, Large, X-Large		Identical
Labeling Claim	1. Low Dermatitis Potential 2. Tested for Use with Chemotherapy Drugs			1. Low Dermatitis Potential 2. Tested for Use with Chemotherapy Drugs		Identical
Biocompatibility	Cytotoxicity compliant as per ANSI/AAMI/ISO 10993-5 Sensitization and irritation compliant as per ISO 10993-10			Sensitization and irritation compliant as per ISO 10993-10		Identical for sensitization and irritation. Our subject device also tested for Cytotoxicity
Modified Draize Test	Under the conditions of the study, there was no clinical evidence of the presence of residual			Under the conditions of the study, there was no clinical evidence of the presence of residual		Identical

	chemical additives that may induce Type IV allergy in the un-sensitized general user populations in the tested articles	chemical additives that may induce Type IV allergy in the un-sensitized general user populations in the tested articles	

8. Summary of Non-Clinical Performance Test

The subject device was tested successfully against:

a) Measurement of Dimensions according to **Standard Practice for Rubber—Measurement of Dimensions ASTM D3767-03 (2014):**
Testing was conducted on lot numbers of each size. All acceptance criteria according **Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D6319-10 (2015)** were met. The number of defective samples was 0; less or equal than the maximum allowable.

b) Measurement of Tensile test according to **Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension ASTM D412-16:**
Testing was conducted on lot numbers of each size. All acceptance criteria according **Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D6319-10 (2015)** were met. The number of defective samples was 0; less or equal than the maximum allowable.

c) Measurement of Residual powder according to **Standard Test Method for Residual Powder on Medical Gloves ASTM D6124-06 (2017):**
Testing was conducted on lot numbers of each size. All acceptance criteria according **Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D6319-10 (2015)** were met. The number of defective samples were 0; less or equal than the maximum allowable.

d) Measurement of Water leak test according to **Standard Test Method for Detection of Holes in Medical Gloves ASTM D5151-06 (2015):**
Testing was conducted on lot numbers of each size. All acceptance criteria according **Standard Specification for Nitrile Examination Gloves for Medical Application ASTM D6319-10 (2015)** were met. In three of the five lots, the number of defective samples was 1; less or equal than the maximum allowable (which is 2 per lot). In two of the three lots, the number of defective samples was zero; less or equal than the maximum allowable.

e) Low dermatitis potential according to **Standard Test Method For Human Repeat Insult Patch Testing Of Medical Gloves ASTM D6355-07:**
Under the conditions of the study, there was no clinical evidence of the presence of residual chemical additives that may induce Type IV allergy in the un-sensitized general user populations in the tested articles.

f) Permeation by Chemotherapy Drugs according to **Standard Practice For Assessment Of Resistance Of Medical Gloves To Permeation By Chemotherapy Drugs ASTM D6978-05 (Reapproved 2013)**
Under the conditions of the study, 15 chemotherapy drugs passed the test, while Carmustine (BCNU) (3.3 mg/ml) failed at 15.9 breakthrough detection time (in minutes), and Thiotepa (10.0 mg/ml) failed at 11.1.

g) Biocompatibility testing was successfully tested in accordance with ANSI AAMI ISO 10993-5:2009/(R)2014 (Cytotoxicity) and ISO 10993-10 Third Edition 2010-08-01 (irritation/sensitization)

9. Summary of Clinical Test

Not applicable.

10. Conclusion

The conclusions drawn from the nonclinical (discussed above) demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device