May 23, 2022

PT. Shamrock Manufacturing Corpora
Jeni Chuason
Regulatory Affairs Manager
JL. Raya Medan - Namorambe Ps IV
Kab. Deli Serdang, North Sumatera 20356
Indonesia

Re: K211810
Trade/Device Name: Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for used 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
Dated: April 12, 2022
Received: April 13, 2022

Dear Jeni Chuason:

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,

Clarence W. Murray, III, PhD
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)*
K211810

Device Name
Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs and Fentanyl)

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

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

Chemotherapy Drug and Permeation
The following chemicals have been tested with these gloves:

Chemotherapy Drug and Concentration	Breakthrough Detection Time in Minutes
Carboplatin (Paraplatin), 10 mg/ml (10,000ppm)	> 240 min.
Carmustine (BCNU), 3.3 mg/ml (3,300ppm)	46.6 min.
Chloroquine 50mg/ml (50,000ppm)	> 240 min
Cisplatin, 1.0 mg/ml (1,000ppm)	> 240 min
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	> 240 min
Dacarbazine, 10.0mg/ml (10,000ppm)	> 240 min
Docetaxel, 10mg/ml (10,000ppm)	> 240 min
Doxorubicin HCI, 2.0mg/ml (2,000ppm)	> 240 min
Etoposide, 20.0mg/ml (20,000ppm)	> 240 min
Fluorouracil, 50.0mg/ml (50,000ppm)	> 240 min
Ifosfamide, 50 mg/ml (50,000 ppm)	> 240 min
Methotrexate, 25mg/ml (25,000 ppm)	> 240 min
Mitomycin C, 0.5 mg/ml (500 ppm)	> 240 min
Paclitaxel, 6.0 mg/ml (6,000 ppm)	> 240 min
Thiotepa, 10.0mg/ml (10,000ppm)	64.8 min
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	> 240 min
Fentanyl Citrate Injection 100mcg/2ml (50mcg/1ml)	> 240 min

Please note that the following drugs that have low permeation time are:

Carmustine (BCNU), 3.3 mg/ml	46.6 min
Thiotepa, 10.0mg/ml	64.8 min

CAUTION: Testing showed an average of breakthrough time of 46.6 min for Carmustine and 64.8 min for 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."

PT. Shamrock Manufacturing Corpora.

Jl. Raya Medan – Namorambe PS. IV Kab. Deli Serdang, Sumatera Utara – Indonesia
Tel. (62-61) 7030008 Fax. (62-61) 7030007
Email: smc@shamrock.co.id

510(k) SUMMARY

Submitter: **PT. SHAMROCK MANUFACTURING CORPORA**
Address: Jl. Raya Medan, Namorambe PS. IV Kab. Deli Serdang
Sumatera Utara, Indonesia
Tel. +62-61 703-0008
Fax. +62-61 703-0007
Contact Person: Imelda/Jeni Chuason
Email: smc@shamrock.co.id

Summary Preparation Date: April 12, 2022

Type of 510(k) Submission: Traditional

Proprietary/Trade Name:
Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl)

Common Name:
Powder Free Nitrile Examination Gloves, Specialty

Regulation Name:
Patient Examination Glove, Specialty (21 CFR 880.6250)

Classification Name:
Patient Exam Glove, Medical Gloves with Chemotherapy / Fentanyl Labeling Claims

Product Code: LZA, LZC, OPJ, QDO

Regulatory Class: Class I

Predicate Device:

YTY Industry (Manjung): Non-sterile, Powder-free Nitrile Examination Gloves (Cobalt Blue) tested for use with Chemotherapy Drugs (K111248)

Device Description:

Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners as a barrier

protection to prevent contamination between a patient and an examiner. The gloves are powder free, ambidextrous, blue color, and beaded cuff.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

The gloves are also complied with requirements for Standard Practice for Assessment of resistance of Medical Gloves to Permeation by Chemotherapy Drugs and Fentanyl as per ASTM D6978-05 (Reapproved 2019).

Indications of Use:

A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs and Fentanyl.

Chemo Drugs tested:	**Breakthrough Time (Minutes)**
Carmustine 3.3 mg/ml (3,300 ppm)	46.6
Chloroquine 50 mg/ml (50,000 ppm)	> 240
Cisplatin 1 mg/ml (1,000 ppm)	> 240
Cyclophosphamide20 mg/ml (20,000 ppm)	> 240
Doxorubicin HCL 2 mg/ml (2,000 ppm)	> 240
Etoposide 20 mg/ml (20,000 ppm)	> 240
Fluorouracil 50 mg/ml (50,000 ppm)	> 240
Paclitaxel 60 mg/ml (6,000 ppm)	> 240
Thiotepa 10 mg/ml (10,000 ppm)	64.8
Carboplatin 10 mg/ml (10,000 ppm)	> 240
Dacarbazine 10 mg/ml (10,000 ppm)	> 240
Docetaxel 10 mg/ml (10,000 ppm)	> 240
Ifosfamide 50 mg/ml (50,000 ppm)	> 240
Methotrexate 25 mg/ml (25,000 ppm)	> 240
Mitomycin C 0.5 mg/ml (500 ppm)	> 240
Vincristine Sulfate 1 mg/ml (1,000 ppm)	> 240
Fentanyl Citrate Injection 100 mcg/2 ml (50 mcg/1mL)	> 240

CAUTION: Testing showed an average of breakthrough time of 46.6 min for Carmustine and 64.8 min for Thiotepa.

Comparison of Technological Characteristics

Comparison of Proposed Device to Predicate Device

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl)	Non-Sterile, Powder-Free Nitrile Examination Gloves (Cobalt) Tested for use within chemotherapy drugs	N/A
510(K) Reference	K211810	K111248	N/A
Product Owner	PT. Shamrock Manufacturing Corpora	YTY Industry (Manjung) SDN, BHD	N/A
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC	Similar
Indications for Use	A patient Examination Glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs	Same
Regulation number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same

PT. Shamrock Manufacturing Corpora.

Jl. Raya Medan – Namorambe PS. IV Kab. Deli Serdang, Sumatera Utara – Indonesia
Tel. (62-61) 7030008 Fax. (62-61) 7030007
Email: smc@shamrock.co.id

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Materials	Powder- Free Nitrile	Powder- Free Nitrile	Same
Color	Blue	Blue	Same
Sizes	x-small, small, medium, large, x-large, xx-large	Medium, Large, Extra-large	Similar
Dimensions Length	Complies with: ASTM D6319-19 220mm min	Complies with: ASTM D6319-10 220mm min	Same
Dimensions Width	Complies with: ASTM D6319-19 70mm min	Complies with: ASTM D6319-10 70mm min	Same
Dimensions Thickness	Complies with: ASTM D6319-19 Palm – 0.05mm min Finger – 0.05mm min	Complies with: ASTM D6319-10 Palm – 0.05mm min Finger – 0.05mm min	Same
Physical Properties	Complies with ASTM D6319-19 Tensile Strength: Before Aging ≥ 14 Mpa (min) After Aging ≥ 14 Mpa (min)	Complies with: ASTM D6319-10 Tensile Strength: Before Aging ≥ 14 Mpa (min) After Aging ≥ 14 Mpa (min)	Same
Physical Properties	Elongation: Before Aging 500% After Aging 400%	Elongation: Before Aging 500% After Aging 400%	Same
Freedom from Holes	Complies with: ASTM D6319-19 ASTM D5151 AQL 2.5	Complies with: ASTM D6319-19 AQL 2.5	Similar
Powder or Powder-free	Powder-free	Powder-free	Same

Residue Powder	Complies with: ASTM D6319-19 < 2 mg per glove	Complies with: ASTM D6319-19 < 2 mg per glove	same
Contact Durations	Limited ≤ 24 hours	Limited ≤ 24 hours	Same
Biocompatibility	ISO 10993-10: Not a skin irritant Not a skin sensitizer ISO 10993-5: Exhibit severe cytotoxicity reactivity ISO 10993-11: Not Toxic	ISO 10993-10: Not a skin irritant Not a skin sensitizer ISO 10993-5: Not available ISO 10993-11: Not available	Different
Sterility	Non-sterile	Non-sterile	Same
Tested Chemotherapy Drugs	Carboplatin 10 mg/ml (10,000 ppm) > 240 min	Carboplatin 10 mg/ml (6,000 ppm) > 240 min	Same
	Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm) > 240 min	Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm) > 240 min	Same
	Docetaxel 10.0 mg/ml (10,000 ppm) > 240 min		Different
	Ifosfamide 50.0 mg/ml (50,000 ppm) > 240 min	Ifosfamide 50.0 mg/ml (50,000 ppm) > 240 min	Same
	Methotrexate 25.0 mg/ml (25,000 ppm) > 240 min	Methotrexate 25.0 mg/ml (25,000 ppm) > 240 min	Same
	Mitomycin C 0.5 mg/ml (500 ppm) > 240 min	Mitomycin C 0.5 mg/ml (500 ppm) > 240 min	Same
	Vincristine Sulfate 1 mg/ml (1,000 ppm) > 240 min		Different
	Carmustine 3.3 mg/ml (3,300 ppm) 46.6 min	Carmustine 3.3 mg/ml (3,300 ppm) 1.82 min	Same

	Chloroquine 50 mg/ml (50,000 ppm) > 240 min		Different
	Cisplatin 1 mg/ml (1,000 ppm) > 240 min	Cisplatin 1 mg/ml (1,000 ppm) > 240 min	Same
	Cyclophosphamide 20.0 mg/ml (20,000 ppm) > 240 min	Cyclophosphamide 20.0 mg/ml (20,000 ppm) > 240 min	Same
	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) > 240 min	Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm) > 240 min	Same
	Etoposide 20.0 mg/ml (20,000 ppm) > 240 min	Etoposide 20.0 mg/ml (20,000 ppm) > 240 min	Same
	Fluorouracil 50.0 mg/ml (50,000 ppm) > 240 min	Fluorouracil 50.0 mg/ml (50,000 ppm) > 240 min	Same
	Paclitaxel 6.0 mg/ml (6,000 ppm) > 240 min	Paclitaxel 6.0 mg/ml (6,000 ppm) > 240 min	Same
	Thiotepa 10.0 mg/ml (10,000 ppm) > 240 min	Thiotepa 10.0 mg/ml (10,000 ppm) > 240 min	Same
Fentanyl Testing	Fentanyl Citrate, 100 mcg/2ml > 240 min		Different

Summary of Non-Clinical Testing

Biocompatibility Testing

Below summary is the biocompatibility results for Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl).

Name of test / citation	Purpose	Acceptance Criteria	Results
ISO 10993-10: Biological Evaluation of Medical Devices, Part 10-Test for Irritation and Skin Sensitization	Irritation Testing	Pass/Fail	Pass Not a skin irritant
ISO 10993-10: Biological Evaluation of Medical Devices, Part 10-Test for Irritation and Skin Sensitization	Sensitization Testing	Pass/Fail	Pass Not a skin sensitizer
Name of test / citation	**Purpose**	**Acceptance Criteria**	**Results**
ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Test for in vitro cytotoxicity	Cytotoxicity Testing	Pass/Fail	Fail Exhibits severe cytotoxicity reactivity
ISO 10993-11: Biological Evaluation of Medical Devices, Part 11: Test for Systemic Toxicity	Systemic Toxicity Testing	Pass/Fail	Pass Not toxic

Permeation Testing

These gloves were tested to support the labeling claim: Tested for use with Chemotherapy Drugs and Fentanyl. The gloves were tested according to ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum breakthrough times were determined for a wide range of chemotherapy drugs and Fentanyl. Below table is the summary of the minimum breakthrough times.

Please note that the following drugs, Carmustine and Thiotepa have low permeation time of 46.6 minutes and 64.8 minutes (less than 240 minutes). Labeling will include caution statement in the presence of these chemotherapy drugs.

Test Chemotherapy Drugs	Average Breakthrough Time
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	> 240 min
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	46.6 min
Cisplatin, 1.0 mg/ml (1,000 ppm)	> 240 min
Cloroquine 50 mg/ml (50,000 ppm)	>2400 min
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	> 240 min
Dacarbazine, 10.0 mg/ml (10,000 ppm)	> 240 min
Docetaxel, 10 mg/ml (10,000 ppm)	> 240 min
Doxorubicin HCI, 2.0 mg/ml (2,000 ppm)	> 240 min
Etoposide, 20.0 mg/ml (20,000 ppm)	> 240 min
Fluorouracil, 50.0 mg/ml (50,000 ppm)	> 240 min
Ifosfamide, 50 mg/ml (50,000 ppm)	> 240 min
Methotrexate, 25 mg/ml (25,000 ppm)	> 240 min
Mitomycin C, 0.5 mg/ml (500 ppm)	> 240 min
Paclitaxel, 6.0 mg/ml (6,000 ppm)	> 240 min
ThioTepa, 10.0 mg/ml (10,000 ppm)	64.8 min
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	> 240 min
Fentanyl Citrate Injection 100 mcg/2ml (50 mcg/1ml)	>240 min

Clinical Test Conclusion

Not applicable

Conclusion

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