March 11, 2019

Sri Trang Gloves (Thailand) Co., LTD
% M. Jordan Smith
Quality Assurance and Regulatory Affairs Leader
Sri Trang USA DBA Ventyv
5401 West Kennedy Boulevard, Suite 760
Tampa, Florida 33609-2447

Re: K182241
Trade/Device Name: Non-sterile, Powder-Free Nitrile Examination Glove Black 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, QDO
Dated: February 14, 2019
Received: February 14, 2019

Dear M. Jordan Smith:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
Date: 2019.03.11 00:18:52 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K182241

Device Name
Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*
This device 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 as follows:
- Carmustine (BCNU) 3.3 mg/mL
- Cisplatin 1.0 mg/mL
- Cyclophosphamide (Cytoxan) 20 mg/mL
- Dacarbazine (DTIC) 10.0 mg/mL
- Doxorubicin Hydrochloride 2.0 mg/mL
- Etoposide (Toposar) 20.0 mg/mL
- Fluorouracil 50.0 mg/mL
- Methotrexate 25 mg/mL
- Paclitaxel (Taxol) 6.0 mg/mL
- Thiotepa 10.0 mg/mL
- Vincristine Sulfate 1.0 mg/mL

Note that Carmustine(BCNU) and Thiotepa have low permeation times.

Fentayl tested as follows:
- Fentanyl citrate 100 mcg/2mL

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.

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510(k) Summary
[As Required by 21 section 807.92 (c)]
K182241

Summary prepared: February 27, 2019

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Contact person – Mr. M. Jordan Smith, Quality Assurance and Regulatory Affairs Leader

Device Trade or Proprietary Name – Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs

Device Common or Usual Name – Examination glove

Device Classification Name – Nitrile Patient Examination Glove (21 CFR 880.6250)

Device Product Codes – LZA, LZC, QDO

Device Class – Class I

Description of the Device – Non-sterile, Powder-Free Nitrile Examination Glove Black Tested for use with Chemotherapy Drugs.

Intended Use of the Device – This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Technological Characteristics Comparison Table –

TECHNOLOGICAL CHARACTERISTICS	**STANDARD**	**PREDICATE DEVICE K083755**	**SUBJECT DEVICE K182241**	**COMPARISON**
Indications for Use	N/A	This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The chemotherapy drugs tested are as follows: Amethopterin Hydrate (Methotrexate), Cisplatin, Cyclphoshamide (Cytoxan), Dacarbazine (DTIC), Doxorubicin Hydrochloride, Etoposide (Toposar), 5-Fluoruracil, Paclitazel (Taxol), and Vincristine Sulfate	This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The tested chemotherapy drugs are as follows: Carmustine (BCNU) Cisplatin, Cyclophosphamide, Dacarbzine (DTIC), Doxorubicin Hydrochloride, Etoposide (Toposar), Fluorouracil, Methotrexate, Paclitaxel (Taxol), Thiotepa, Vincristine Sulfate Note Carmustine (BCNU) and Thiotepa have low permeation times Fentanyl tested as follows: Fentanyl Citrate	Nearly Identical
Dimensions: overall length	Minimum 230 mm	244 mm	238 mm 238 mm	Identical

	ASTM-D 6319	242 mm 242 mm	238 mm	
Dimensions: width (mean)	110 ± 10 mm ASTM-D 6319	Size Large 113 mm 114 mm 114 mm	Size Large 114 mm 115 mm 114 mm	Identical
Dimensions: palm and finger thickness	Minimum 0.05 mm ASTM-D 6319	Palm 0.06 mm 0.07 mm 0.07 mm Finger 0.09 mm 0.07 mm 0.08 mm	Palm 0.07 mm 0.07 mm 0.07 mm Finger 0.08 mm 0.08 mm 0.09 mm	Identical
Tensile strength: before and after aging	Greater than 14 MPa ASTM-D 6319	Before 40 MPa 40 MPa 41 MPa After 39 MPa 40 MPa 41 MPa	Before 35 MPa 33 MPa 35 MPa After 31 MPa 32 MPa 34 MPa	Identical
Ultimate elongation: before and after aging	Greater than 500% Before, 400% After ASTM-D 6319	Before 564% 584% 580% After 580% 580% 616%	Before 538% 534% 535% After 518% 493% 503%	Identical
Freedom from holes: pinholes AQL 2.5	Inspection G1, AQL 2.5 7 Accept 8 Reject ASTM-D 6319	3 2 3	0 2 0	Identical

Powder Free Residue	ASTM-D 6319	0.5 mg/glove 0.3 mg/glove 0.2 mg/glove	0.7 mg/glove 0.8 mg/glove 0.8 mg/glove	Identical
Biocompatibility	ISO 10993-5 *In vitro* cytotoxicity ISO 10993-11 Tests for systemic toxicity	N/A	Under the conditions of the study, the device extract was found to be cytotoxic and therefore the device extracts were evaluated by ISO 10993-11 - Test for systemic toxicity. From the Acute Systemic Toxicity device extracts, the device extracts did not elicit a systemic response in the animal model.	Identical
	ISO 10993-10 Primary Skin Irritation in Rabbits	Under the conditions of the study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Under the conditions of the study, the polar and non-polar device extracts were found not to be an irritant to the animal model.	Same
	Guinea Pig Sensitization	Under the conditions of the study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Under the conditions of the study, the polar and non-polar device extracts were found not to be sensitizers to the animal model.	Same

Summary of Non-Clinical Performance Testing – Non-clinical tests were conducted to demonstrate that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

- ASTM D412-2006a (reapproved 2013) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
- ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven
- ASTM D3767-03 Standard Practice for Rubber Measurement of Dimensions
- ASTM D5151-2006 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-2006 (Reapproved 2001) Standard Tested Method for Residual Powder on Medical Gloves
- ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes
- ISO 10993-5 Biological evaluation of medical devices-Part5 Tests for *in vivo* cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices-Part 10 Test for irritation and delayed-type hypersensitivity
- ISO 10993-10 Biological evaluation of medical devices-Part 11 Tests for systemic toxicity

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