December 21, 2021

Koon Seng Sdn Bhd
% Wava Truscott
President
Truscott MedSci Associates, LLC.
180 Burkemeade Ct.
Roswell, Georgia 30075

Re: K212613
Trade/Device Name: Powder Free Nitrile Examination Gloves, Non-sterile,Tested For Use with Chemotherapy Drugs and Opioid Fentanyl Citrate (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QPO
Dated: November 15, 2021
Received: November 22, 2021

Dear Wava Truscott:

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)*

K212613

Device Name

Trade Name: Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs and the Opiod Fentanyl Citrate (Blue)

Indications for Use *(Describe)*: A Nitrile powder free examination glove is a disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between examiner and patient. This specialty glove has also been tested with Chemotherapy drugs and the Opioid Fentanyl citrate.

Chemotherapy Drugs and the opioid Fentanyl citrate were tested for breakthrough detection times:

TEST CHEMOTHERAPY DRUG	CONCENTRATION TESTED	MINIMUM BREAKTHROUGH DETECTION TIME (MINUTES)
Carmustine (BCNU)	3.3 mg/ml	13.0
Cisplatin	1.0 mg/ml	No Breakthrough Up To 240 minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml	No Breakthrough Up To 240 minutes
Cytarabine	100.0 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 (Toposar)	20.0 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
Methotrexate	25.0 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
Paclitaxel (Taxol)	6.0 mg/ml	No Breakthrough Up To 240 minutes
Thiotepa	10.0 mg/ml	37.9
Vincristine Sulfate	1.0 mg/ml	No Breakthrough Up To 240 minutes

Important: Carmustine and Thiotepa have extremely low minimal breakthrough times of 13.0 minutes and 37.9 minutes respectively. **Warning**: Do not use with Carmustine or Thiotepa.

TEST OPIOID DRUG	CONCENTRATION TESTED	MINIMUM BREAKTHROUGH DETECTION TIME (MINUTES)
Fentanyl Citrate (Injectable)	100.0 mg/2ml	No Breakthrough up to 240 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.

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K212613:
510(k) Summary

1.0 Submitter

Name	:	Koon Seng, Sdn. Bhd.
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Phone No.	:	+603-7733 1388
Fax No.	:	+603-7733 6499
Date of Preparation	:	June 29, 2021

2.0 Name of the Device

Common Name	:	Nitrile Powder Free Examination Glove
Trade Name	:	Powder Free Nitrile Examination Gloves, Non-sterile,Tested for Use with Chemotherapy Drugs and the Opioid Fentanyl Citrate (Blue)
Classification Name	:	Patient Examination Glove Specialty (21CFR 880.6250)
Product Codes	:	LZA, LZC, OPJ, QDO
Device Class	:	Class I

3.0 Predicate: Identification of Legally Marketed Device

Predicate 510(k) No.	:	K192954
Trade Name	:	Blue Colored, Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Owner	:	Comfort Rubber Gloves Industries Sdn. Bhd.
Product Codes	:	LZA, LZC, QDO
Device Class	:	Class I

4.0 Description of Subject Device

The K212613 gloves are produced as nitrile synthetic gloves. They are manufactured without natural rubber latex. The nitrile gloves are blue in color, disposable, single-use only, non-sterile, medical examination gloves. K212613 meets all the requirements of ASTM D6978-10(2019) Standard Specifications for Examination Gloves for Medical Applications. They have been tested for use with chemotherapy drugs and the opioid Fentanyl citrate, both of which were evaluated using ASTM D6378-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

5.0 Indications for Use

A Nitrile powder free examination glove is a disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between examiner and patient. This specialty glove has also been tested for use with Chemotherapy drugs and the Opioid Fentanyl citrate.

Test Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU)	3.3 mg/mL	13 min.
Cisplatin	1.0 mg/mL	>240 min.
Cyclophosphamide (Cytoxan)	20.0 mg/mL	>240 min.
Cytarabine	100 mg/mL	>240 min.
Dacarbazine	10.0 mg/mL	>240 min.
Doxorubicin	2.0 mg/mL	>240 min.
Etoposide	20.0 mg/mL	>240 min.
Fluorouracil	50.0 mg/mL	>240 min.
Ifosfamide	50.0 mg/mL	>240 min.
Methotrexate	25.0 mg/mL	>240 min.
Mitomycin C	0.5 mg/mL	>240 min.
Mitoxantrone	2.0 mg/mL	>240 min.
Paclitaxel	6.0 mg/mL	>240 min.
ThioTepa	10.0 mg/mL	37.9 min
Vincristine Sulfate	1.0 mg/mL	>240 min.
Important: Carmustine and ThioTepa have extremely low minimum breakthrough times of 13.0 minutes and 37.9 minutes respectively. **Warning:** Do not use with Carmustine or ThioTepa.		
Test Opioid Drug	Concentration	Minimum Breakthrough Detection Time (minutes)
Fentanyl Citrate Injection	100mcg/2mL	>240 min.
Please Note: Glove used for protection against possible Chemotherapy Drug exposure should be selected specifically for the type of drugs used. Users should review drug labeling or material safety data sheets for the drugs being used to determine an adequate level of protection.		

Technological Characteristic Comparison:

Shown below is a comparison of The Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs and Opioid Fentanyl Citrate (Blue) and Blue Colored, Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.

Glove Comparison Table:

Subject	Standards	Koon Seng Subject Device 510(k): K212613	Predicate Device: 510(k): K192954	Comparison K212613 Subject glove to Predicate K192954
Manufacturers	NA	Koon Seng Sdn. Bhd.	Comfort Rubber Gloves Industries Sdn. Bhd.	Different
Trade Name	**NA**	Powder Free Nitrile Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and the Opiod Fentanyl Citrate (Blue)	Blue Colored, Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Different
Common Name	ASTM D6319 - 10(2019)	Nitrile Powder free Patient Examination Glove	Nitrile Patient Examination Glove	Similar
Device Class	21 CFR 880.6250	Class 1	Class 1	Same
Base Material	NA	Nitrile	Nitrile	Same
Color	NA	Blue	Blue	Same
Product Codes	21 CFR 880.6250	LZA, LZC, OPJ, QDO	LZA, LZC, QDO	Similar OPJ is new: denotes tested with Chemotherapy drugs to further define the LZC specialty designation
Sizes offered	ASTM D3767	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Dimensions:	ASTM D6319 - 10(2019)	Meets	Meets	Same
Sterile v. Non-Sterile	NA	Non-Sterile	Non-Sterile	Same
Prescription or OTC	NA	OTC	OTC	Same
Single Use-Disposable	NA	Single use-Disposable	Single use-Disposable	Same
Thickness: Finger & palm	ASTM D6319 - 10(2019)	Meets	Meets	Same
Before aging Physical Properties	ASTM D412 ASTM D6319 - 10(2019)	Meets	Meets	Same
After aging Physical Properties	ASTM D412 ASTM D6319	Meets	Meets	Same
Freedom from Holes	ASTM D5151 ASTM D6319	Meets AQL 1.5	Meets AQL 1.5	Same

Subject	Standards	Koon Seng Subject Device 5l0(k): K212613	Predicate Device: 510(k): K192954	Comparison K212613 Subject glove to Predicate K192954
Powder-Free	ASTM D6124 < 2mg/glove	Meets	Meets	Same
Intended Use (part of Indications for Use)		A Nitrile powder free examination glove is a disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between examiner and patient. This specialty glove has also been tested for use with Chemotherapy drugs and the Opioid Fentanyl citrate.	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Indications for Use Chemotherapy	ASTM D6978	**Chemotherapy drugs:** **All >240min Breakthrough Times except Carmustine & ThioTEPA** • Cisplatin, 1mg/ml • Cyclophosphamide (Cytoxan), 20mg/ml • Cytarabine, 100mg/ml • Dacarbazine, 10mg/ml • Doxorubicin HCL, 2mg/ml • Etoposide, 20mg/ml • Fluorouracil, 50mg/ml • Ifosfamide, 50mg/ml • Methotrexate, 25mg/ml • Mitomycin C, 0.5mg/ml • Mitoxantrone, 2mg/ml • Paclitaxel, 6mg/ml • Vincristine Sulfate,mg/ml • Carmustine (BCNU), 3.3 mg/ml: **Breakthrough:** 13 min. • ThioTepa, 10mg/ml **Breakthrough:** 37.9 min.	**Chemotherapy drugs:All >240min Breakthrough Times except Carmustine & ThioTEPA** • Cisplatin 1mg/ml • Cyclophosphamide (Cytoxan) 20mg/ml • Dacarbazine (DTIC) 10 mg/ml • Doxorubicin HCL, 2mg/ml • Hydrochloride 2mg/ml • Etoposide (Toposar) 20mg/ml • FluorouracilS0mg/ml • Paclitaxel (Taxol) 6mg/ml • Carmustine (BCNU) 3.3 mg/ml: **Breakthrough:** 18.2 min. • ThioTepa (THT) 10mg/ml: **Breakthrough:** 57.3 min.	Similar

Subject	Standards	Koon Seng Subject Device 5l0(k): K212613	Predicate Device: 5l0(k): K192954	Comparison K212613 Subject glove to Predicate K192954
Cautions & **Warnings**		**Important:** Carmustine and ThioTEPA have extremely low minimal breakthrough times of 13.0 minutes and 37.9 minutes respectively. **Warning:** Do not use with Carmustine or ThioTepa	**Please note** that the following drugs have extremely low permeation times: Carmustine (BCNU): 18.2minutes and Thiotepa: 57.3 minutes. **Warning:** Do not use with Carmustine.	Similar: except Subject device added ThioTepa to the "**Warning:** Do not use with..." listing. Technically, it is not required to do so as the cut-off to require the warning is below 30 minutes.
Indications for Use: Fentanyl	ASTM D6978	Fentanyl Citrate (Injectable) 100mg/2ml:Minimum breakthrough time: >240	Fentanyl Citrate 100mg/2ml: Minimum breakthrough time: >240	Similar: Fentanyl Citrate concentration & diluent same. US DEA required testing street injectable term by test lab in test results
Biocompatibility	**ISO 10993-11: Tests** for **Systemic Toxicity**	Passes Under the conditions of The Systemic Toxicity test the predicate glove showed no adverse biological reaction.	(Used Accepted Alternative: ISO 10993-5 (Cytotoxicity)	Similar: Used Different alternative biocompatibility test method: Both acceptable
	ISO 10993-5 Cytotoxicity	(Used Accepted Alternative: ISO 10993-11 Acute Systemic Toxicity)	Passed at: Exhibits severe cytotoxicity reactivity at 100%, and 66% extract concentrations and no cytotoxicity reactivity at 44%, 30%, 20% and 15% extract concentrations under the condition of this test.	Similar: Used Different Accepted Alternative Biocompatibility test
	ISO 10993-10 Skin Irritation	Passes Under conditions of this study, subject glove is non-irritating	Passes Under conditions of the study, the device is non-irritating	Same
	ISO 10993-10 Dermal Sensitization	Passes Under conditions of this study, subject glove is a non-sensitizer	Passes Under conditions of the study, the device is non-sensitization	Same

Summary of Non-Clinical Performance Tests conducted

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6978-2005 (2019)	Permeation by Chemotherapy Drugs	Minimum detection time >240 minute	All Chemotherapy Drugs & the Opioid Passed >240min. except Carmustine & ThioTepa
ASTM D412-2016 ASTM D573-04(2019)	Physical properties	Tensile strength (min=14Mpa); Elongation (min 400%)	Pass
ASTM D5151-19	Water-leak test	AQL 1.5 (ISO 2859-1)	Pass
ASTM D6124-06(2017)	Residual powder test	≤2mg/glove	Pass
ISO 10993-10:2010 (2016)	Dermal Irritation	Under conditions of this study, the subject device is non-irritating	Pass
ISO 10993-10:2010 (2016)	Skin Sensitization	Under conditions of this study, the subject device is non-sensitizing	Pass

Non-clinical performance testing method full Titles:

- ASTM D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers— Tension
- ASTM D573 Test Method for Rubber—Deterioration in an Air Oven x ASTM D3578 Specificationfor Rubber Examination Gloves
- ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151 Test Method for Detection of Holes in Medical Gloves
- ASTM D6124 Test Method for Residual Powder on Medical Gloves
- ISO 2859 Sampling Procedures and Tables for Inspection by Attributes Test results show that under the conditions of the testing, there is no difference in physical attributes between the proposed device and the predicate device.
- ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Biocompatibility Testing was performed utilizing: ISO 10993 Biological Evaluation of Medical Devices

- ISO 10993 - Part 10: Tests for Irritation and Sensitization. Both Skin Irritation and Dermal Magnuson/Kligman Sensitization performed.
- ISO 10993 – Part 11: Tests for assessment of Systemic Toxicity

No human clinical or animal performance testing was performed.

Conclusion: The conclusions drawn from comparing the physical attributes and 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.