June 21, 2021

Duramitt sdn Bhd
Terence Lim
RA Specialist
No. 3, Jalen Baling Padong Meha Industrial Estate
Padang Serai
Kulim, Kedah 09400
Malaysia

Re: K210375
Trade/Device Name: Powder Free Blue Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 16, 2021
Received: May 24, 2021

Dear Terence Lim:

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,

Ryan Ortega, PhD
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K210375

Device Name

Powder Free Blue Nitrile Examination Glove

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Attachment 3

510 (K) SUMMARY SHEETS

1.0 510 (K) SUMMARY

2.0 Submitter

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Date of Summary Prepared:	January 17, 2021

3.0 Name of Device:

510(k) number	K210375
Trade Name:	Powder Free Blue Nitrile Examination Glove
Classification Name:	Polymer Patient Examination Glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LZA

4.0 Identification of The Legally Marketed Device

Predicate Device Name: Powder Free Blue Nitrile Examination Glove

Predicate 510(K) Number: K153562

Manufacturer's Name: VIETGLOVE CORPORATION

5.0 Description of Device

Powder Free Blue Nitrile Examination Glove meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. The principle operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the counter single use.

6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

7.0 Summary of the Technological Characteristic of the Device compared to the Predicate Device for Substantial Equivalent Discussion.

There is no difference in technology characteristic compared to the predicate device. Gloves are made from nitrile latex compound. Non-Sterile, Powder Free Blue Nitrile Examination Gloves has the below technological characteristic compared to ASTM or Equivalent standards.

Comparison between Proposed Device & Predicate Device

Characteristics and Parameters	Proposed Device - Powder Free Nitrile Examination Gloves (K210375)	Predicate Device - Powder Free Blue Nitrile Examination Gloves (K153562)	Discussion
Product Code	LZA	LZA	Same product Code
Intended Use	*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*	*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*	Same Intended Use.
Classification	Class 1	Class 1:	Same Class. .
Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same synthetic rubber material.
Surface Appearance	1. Blue 2. Ambidextrous 3. Finger Textured	1. Blue 2. Ambidextrous 3. Finger Textured	Same color, ambidextrous design and same texture area.
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1.	Similar
Overall Length Minimum 230mm	Average : S : 242 mm M : 242 mm L : 243 mm	More than 230mm	Similar
Width S : 75mm – 95mm M: 85mm – 105mm L: 100mm – 120mm	Average : S : 84 mm M : 96 mm L : 107 mm	Meeting specification	Similar
Palm Thickness (Minimum 0.05mm)	Average : S : 0.06 mm M : 0.06 mm L : 0.06 mm	More than 0.05mm	Similar
Finger Thickness (Minimum 0.05mm)	Average : S : 0.08 mm M : 0.08 mm L : 0.08 mm	More than 0.05mm	Similar
Tensile Strength (before age) Minimum 14 MPa	Average : S : 19.37 MPa M : 19.04 MPa L : 19.81 MPa	More than 14 MPa	Similar
Tensile Strength (After Age) Minimum 14 MPa	Average : S : 84 mm M: 94mm L 103mm	More than 14 MPa	Similar

Characteristics and Parameters	Proposed Device - Powder Free Nitrile Examination Gloves (K210375)	Predicate Device - Powder Free Blue Nitrile Examination Gloves (K153562)	Discussion
Ultimate Elongation before age (Minimum 500%)	Average : S : 560% M : 560% L : 560%	Minimum 500%	Similar
Ultimate Elongation after age (Minimum 400%)	Average : S : 500% M: 510% L : 510%	Minimum 400%	Similar
Residual powder test (Less than 2mg/glove)	Average powder residue for each size: S : 0.61 mg/glove M : 0.59 mg/glove L : 0.57 mg/glove	Contained less than 2mg/glove	Similar
Primary Skin Irritation	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Similar
Dermal Sensitization	Under the conditions of study, not a sensitizer.	Under the conditions of study, not a sensitizer.	Similar
Acute Systemic Toxicity	Not induce systemic toxicity	Not done	Meeting the requirements per ISO 10993-11

Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed

Device complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ASTM D6124-06,Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application
- ISO 2859-1:1999, “Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6124	To check the amount of powder residue from glove surface	Less than 2mg/glove	Pass
ASTM D5151	To detect the presence of hole in glove	Meet AQL 2.5 from sampling of the lot	Pass
ASTM D6319	To measure the following physical parameters of the glove a) Length b) Palm Thickness c) Tensile Strength before age d) Tensile Strength after age e) Elongation before age f) Elongation after age	a) Length at minimum 230mm b) Palm Thickness at minimum 0.05mm c) Tensile strength before age at minimum 14MPa d) Tensile Strength after age at minimum 14MPa e) Elongation before age at minimum 500% f) Elongation after age at minimum 400%	Pass
ISO 10993	To determine the irritation potential of glove when expose to skin surface and also to evaluate whether residual chemical additives at the level that may induce Type IV allergy a) Primary Skin Irritation Test b) Skin Sensitization Test	a) Not an Irritant b) Not a Sensitizer	Pass
ISO 10993-11	To evaluate the human hazard potential from glove	a) Not induce systemic toxicity	Pass

Clinical Test Conclusion

No clinical test is included in this submission.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates the subject device in 510(K) submission K210375, Powder Free Nitrile Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153562.