July 8, 2022

KGM Gloves Sdn. Bhd.
Ooi Seng
RA Manager
Lot 18893 & 18894, Jalan Perusahaan 9, Kawasan Perusahaan
Kamunting, Perak 34600
Malaysia

Re: K220284
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 10, 2022
Received: May 16, 2022

Dear Ooi Seng:

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)*
K220284

Device Name
Powder Free Nitrile Examination Gloves (Blue)

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1.0 510 (K) SUMMARY 510(k) Number: K220284

2.0 Submitter:

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Date of Preparation : January 15, 2022

3.0 Name of the Device

Trade Name: Powder Free Nitrile Examination Glove (Blue)
Classification Name: Patient Examination Glove
Device Classification: Class I
Regulation Number: 21 CFR 880.6250
Product Code: LZA

4.0 Identification of The Legally Marketed Predicate Device

Predicate Device Name: Powder Free Blue Nitrile Examination Glove
Predicate 510(K) Number: K210375
Manufacturer's Name: Duramitt Sdn. Bhd.
Device Classification: Class I
Regulation Number: 21 CFR 880.6250
Product Code: LZA

5.0 Description of Device

Powder Free Blue Nitrile Examination Glove meets all the current specifications listed under the ASTM Specification D6319-19, 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 Device

The Powder Free Nitrile Examination Glove (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

7.0 Summary of the Technological Characteristic Comparison of the Device

Provided below is a comparison of the subject device and the predicate device

Characteristics and Parameters	Proposed Device - Powder Free Nitrile Examination Gloves	Predicate Device - Powder Free Blue Nitrile Examination Gloves (K210375)	Comparison
Product Code	LZA	LZA	Identical
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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.	Identical
Device Classification	Class I	Class I	Identical
Device material	Nitrile (Acrylonitrile butadiene)	Nitrile (Acrylonitrile butadiene)	Similar
Colour	Blue	Blue	Similar
Instruction for Use on Labeling	Single Use only.	Single Use only.	Identical
Construction	Ambidextrous	Ambidextrous	Identical
Freedom from holes	Meet AQL 2.5 at G1	Meet AQL 1.5 at G1	Same
Length: XS-Minimum 220mm S-Minimum 220mm M-Minimum 230mm L-Minimum 230mm XL-Minimum 230mm	Minimal Value for Length: **XS: 240mm** **S: 246mm** **M: 240mm** **L : 250mm** **XL: 251mm**	Average XS:- S: 242mm M: 242mm L : 243mm XL:-	Similar
Width:- XS-70 ± 10mm S-80 ± 10mm M-95 ± 10mm L-110 ± 10mm XL-120 ± 10mm	Minimal Value for Width: **XS: 73mm** **S: 84 mm** **M: 93 mm** **L: 104 mm** **XL: 111mm**	Average XS:- S: 84mm M: 96mm L : 107mm XL:-	Similar
Palm Thickness Minimum 0.05mm	Palm Minimal Value: **XS: 0.07mm** **S: 0.07mm** **M: 0.07mm**	Average XS:- S: 0.06mm M: 0.06mm	Similar

	L : 0.07mm **XL: 0.07mm**	L : 0.06mm XL:-	
Finger Thickness Minimum 0.05mm	Finger Minimal Value: **XS: 0.11mm** **S: 0.11mm** **M: 0.11mm** **L : 0.11mm** **XL: 0.12mm**	Average XS:- S: 0.08mm M: 0.08mm L : 0.08mm XL:-	Similar
Tensile Strength (Before age) Minimum 14.0MPa	Minimum 19.1MPa	Average 19.04MPa	Similar
Tensile Strength (After Age) Minimum 14.0MPa	Minimum 19.0MPa	Minimum 14.0MPa	Different
Ultimate Elongation (Before age) Minimum 500%	Minimum 520%	Average 560%	Similar
Ultimate Elongation (After age) Minimum 400%	Minimum 480%	Average 510%	Similar
Residual powder test (≤2mg/glove)	Average 0.10mg/glove	Average 0.59mg/glove	Similar
Primary Skin Irritation	Under the condition of study, not an irritant	Under the condition of study, not an irritant	Same
Dermal Sensitization	Under the condition of study, not a sensitizer	Under the condition of study, not a sensitizer	Same
Acute Systemic Toxicity	Not induce systemic toxicity	Not induce systemic toxicity	Same

8.0 Summary of Non-Clinical Performance Data

Provided in the table below is the summary of the non-clinical testing performed with the subject device. The results demonstrate that the subject device met the acceptance criteria.

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319-19: Dimensions	To measure the physical length and width of the gloves	Length: XS-Minimum 220mm S-Minimum 220mm M-Minimum 230mm L-Minimum 230mm XL-Minimum 230mm	Minimal Value for Length: **XS: 240mm** **S: 246mm** **M: 240mm** **L : 250mm** **XL: 251mm**

		Width: XS-70 ± 10mm S-80 ± 10mm M-95 ± 10mm L-110 ± 10mm XL-120 ± 10mm	Minimal Value for Width: **XS: 73mm** **S: 84 mm** **M: 93 mm** **L: 104 mm** **XL: 111mm** **PASS**
ASTM D6319-19: Physical Properties	To measure the tensile strength and elongation before and after aging	Tensile Strength: Before Aging: 14.0 MPa After Aging: 14.0 MPa Ultimate Elongation: Before Aging: min. 500% After Aging: min. 400%	Tensile Strength: Before Aging: Minimal Value: 19.10 MPa After Accelerated Aging: Minimal Value: 19.0 MPa Ultimate Elongation: Before Aging Minimal Value: 520% After Aging Minimal Value: 480% **PASS**
ASTM D6319-19: Thickness	To measure the physical palm and finger thickness of the gloves	Palm-Min. 0.05mm Finger-Min. 0.05mm	Palm Minimal Value: **XS: 0.07mm** **S: 0.07mm** **M: 0.07mm** **L : 0.07mm** **XL: 0.07mm** Finger Minimal Value: **XS: 0.11mm** **S: 0.11mm** **M: 0.11mm** **L : 0.11mm** **XL: 0.12mm** **PASS**

ASTM D6319-19: Freedom from Holes Testing	To detect the presence of hole in glove	Meet AQL 2.5 at G1	Meet AQL 2.5 at G1 **PASS**
ISO 10993-10: Primary Skin Irritation	To determine the irritation potential of glove when expose to skin surface.	Not an irritant	Under the condition of study, not an irritant **PASS**
ISO 10993-10: Dermal Sensitization	To determine the sensitization potential of glove when expose to skin surface	Not a Sensitizer	Under the condition of study, not a sensitizer **PASS**
ISO 10993-11: Acute Systemic Toxicity	To evaluate the adverse systemic reaction potential from glove	Not induce systemic toxicity	Did not induce systemic Toxicity **PASS**
ASTM D6124-06: Residual Powder Analysis	To check the amount of powder residue from glove surface	Residual powder test (≤2mg/glove)	Average 0.10mg/glove **PASS**

9.0 Summary of Clinical Performance Data

Not applicable - Clinical data is not needed for the subject device, gloves.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K210375.