DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 8, 2017

Professional Latex Sdn Bhd
Mr. Terence Lim
Regulatory Affairs Manager
Lot 52, Jalan Logam 2, Kamunting Raya lndustrial
Kamunting, 34600 MY

Re: K171667
Trade/Device Name: Powder Free Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: August 10, 2017
Received: August 10, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171667

Device Name
Powder Free 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Professional Latex Sdn Bhd
Lot 52, Jalan Logam 2, Kamunting Raya Industrial, 34600 Kamunting, Perak

510(k)#: K171667

1.0 510 (K) SUMMARY

2.0 Submitter

Professional Latex Sdn Bhd
Lot 52, Jalan Logam 2, Kamunting Raya Industrial
34600 Kamunting, Perak

Tel:	+605 - 891 1637
Fax:	+605 - 891 1417
Name of Contact Person:	Terence Lim
Email Address:	Terencelim@professionallatex.com
Date of Summary Prepared:	September 3, 2017

3.0 Name of Device:

Trade Name:	Powder Free 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: RS SAFE BLUE NITRILE MEDICAL EXAMINATION GLOVES (POWDER FREE)

Predicate 510(K) Number: K100603

Manufacturer's Name: Riverstone Resources Sdn Bhd
Jalan Jasmin 2 48300 Bukit Beruntung

5.0 Description of Device

Non-Sterile, Powder Free Nitrile Examination Gloves – Blue 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 Nitrile Examination Gloves, Blue, has the below technological characteristic compared to ASTM or Equivalent standards.

Characteristics and Parameters	Powder Free Nitrile Examination Gloves (K171667)	Powder Free Nitrile Examination Gloves (K100603)	Comparison
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 I	Class I	Same
Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same
Surface Appearance	1. Blue 2. Ambidextrous 3. Finger Textured	1. Blue 2. Ambidextrous 3. Finger Textured	Similar
Overall Length Minimum 230mm	Average: 242 mm	240 – 250 mm (specification sheet)	Similar
Width S : 75mm – 95mm M: 85mm – 105mm L:100mm – 120mm	Average: S: 85mm M: 95mm L: 104mm	S : 83 – 86 mm M : 93 – 96 mm L : 102 – 105 mm (specification Sheet)	Similar
Palm Thickness (Minimum 0.05mm)	Average: 0.06mm	0.07 - 0.09 mm (specification sheet)	Similar

Characteristics and Parameters	Powder Free Nitrile Examination Gloves (K171667)	Powder Free Nitrile Examination Gloves (K100603)	Comparison
Finger Thickness (Minimum 0.05mm)	Average: 0.07mm	0.10 - 0.13 mm (specification sheet)	Similar
Tensile Strength (before age) Minimum 14 MPa	Average: 17.44 MPa	More than 17 MPa (Specification Sheet)	Similar
Tensile Strength (After Age) Minimum 14 MPa	Average: 16.37 MPa	More than 16 MPa (Specification Sheet)	Similar
Ultimate Elongation before age (Minimum 500%)	Average: 559%	500% - 600% (Specification Sheet)	Similar
Ultimate Elongation after age (Minimum 400%)	Average: 508%	400% - 500% (Specification Sheet)	Similar
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1.	Same
Residual powder test (Less than 2mg/glove)	Average powder residue for each size: S: 0.43 mg/glove M: 0.31 mg/glove L: 0.47 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	Same
Dermal Sensitization	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer.	Same

8.0 Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

9.0 Clinical Performance Data

Not applicable - Clinical data is not needed for gloves

10.0 Conclusion

Powder Free Nitrile Patient Examination Glove, Non-Sterile is as safe and as effective and substantially equivalent to the predicate device.