June 6, 2018

Professional Latex Sdn Bhd
Terence Lim
Regulatory Affairs Manager
Lot 52, Jalan Logam 2, Kamunting Raya lndustrial
Kamunting, Perak 34600
Malaysia

Re: K173053
Trade/Device Name: Powder Free Latex Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYY
Dated: April 30, 2018
Received: May 7, 2018

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. 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.

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.

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,

Geeta K.
Pamidimukkala -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173053

Device Name
Powder Free Latex 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) SUMMARY

1.0 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:	May 31, 2018

2.0 Name of Device:

510k no.	K173053
Trade Name:	Powder Free Latex Examination Glove
Classification Name:	Non-Powder Patient Examination Glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LYY

3.0 Identification of The Legally Marketed Device

Predicate Device Name: LATEX EXAMINATION GLOVES POWDER FREE

Predicate 510(K) Number: K161833

Manufacturer's Name: CAREGLOVE GLOBAL SDN BHD

4.0 Description of Device

Powder Free Latex Examination Gloves meets all the current specifications listed under the ASTM Specification D3578-05, Standard Specification for Rubber Examination Gloves. 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.

5.0 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

6.0 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 natural rubber latex compound. Non-Sterile, Powder Free Latex Examination Gloves has the below technological characteristic compared to ASTM or Equivalent standards.

Characteristics and Parameters	**Powder Free Latex Examination Glove (K173053)**	**Powder Free Latex Examination Glove (K161833)**	**Comparison**
Product Code	LYY	LYY	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. Meeting 21 CFR 880.6250 requirement.
Classification	Class 1	Class 1:	Same.
Raw Rubber Material	Natural Rubber Latex	Natural Rubber Latex	Same base material.
Colour	No colour pigment added. Natural White	No colour pigment added.Natural White	Similar.
Overall Length Minimum 230mm	Average: 242 mm	Meet ASTM D3578-05	Similar. Meeting requirement of length under ASTM D 3578-05
Width S: 75mm – 95mm M: 85mm – 105mm L:100mm – 120mm	Average: S: 85 mm M: 95mm L:104mm:	S: 82mm – 87 mm M: 94mm – 97 mm L: 102mm – 107mm	Similar. Meeting requirement of Width under ASTM D 3578-05
Palm Thickness (Minimum 0.08mm)	Average: 0.09mm	0.12mm - 0.14 mm	Similar. Meeting requirement of Palm thickness under ASTM D 3578-05
Finger Thickness (Minimum 0.08mm)	Average: 0.11 mm	0.10 - 0.13 mm	Similar. Meeting requirement of Palm thickness under ASTM D 3578-05

Characteristics and Parameters	Powder Free Latex Examination Glove (K173053)	Powder Free Latex Examination Glove (K161833)	Comparison
Tensile Strength (before age) Minimum 18 MPa	Average: 23.65 MPa	21.18 – 26.17 MPa	Similar. Meeting requirement of Tensile Strength under ASTM D 3578-05
Tensile Strength (After Age) Minimum 14 MPa	Average: 20.99 MPa	18.28 – 23.88 MPa	Similar. Meeting requirement of Tensile Strength under ASTM D 3578-05
Stress at 500% Elongation 5.5 MPa Maximum	3.5 MPa	3.0 – 4.2 MPa	Similar. Meeting requirement of Tensile Strength under ASTM D 3578-05
Ultimate Elongation before age (Minimum 500%)	Average: 734%	750.20% – 820.20%	Similar. Meeting requirement of Tensile Strength under ASTM D 3578-05
Ultimate Elongation after age (Minimum 400%)	Average: 622%	550.40% - 700.50%	Similar. Meeting requirement of Tensile Strength under ASTM D 3578-05
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 2.5 with G1	Meet AQL 2.5 with G1.	Similar. Meeting requirements of Freedom of Holes under ASTM D 3578-05
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. Meeting requirement of powder residue under ASTM D 3578-05
Protein Testing	S size: Less than 50 µg/dm^2 M size: Less than 50 µg/dm^2 L size: Less than 50 µg/dm^2	less than 50 µg/dm^2	Similar. Meeting requirement of protein level under ASTM D 3578-05
Primary Skin Irritation	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Same. Both are tested to be non-irritant. Under ISO 10993 -10
Dermal Sensitization	Under the conditions of study, not a sensitizer.	Under the conditions of study, not a sensitizer.	Same. Both are tested to be non-sensitizer.

			Under ISO 10993-10
Cytotoxicity	Under the condition of the study, the extract from the device is non- cytotoxic to L-929 cells	Not available	The subject device extract is non-cytotoxic to L-929 cells under ISO 10993-5

7.0 Non-Clinical Performance Data

The performance test data of the non-clinical tests is reported in the table above.

8.0 Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed.

9.0 Conclusion

From the non-clinical tests, it can be concluded that the Powder Free Latex Examination Glove, Non-Sterile, is as safe and as effective and performs as well or better than the legally marketed preeicate device.