DEPARTM'ENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 23, 2017

Pt. Maja Agung Latexindo
% Emmy Tjoeng
Marketing Director
Shamrock Manufacturing Co. Inc.
5445 Daniels Street
Chino, California 91710

Re: K161099
Trade/Device Name: Powder Free Nitrile Examination Gloves, Black
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: January 17, 2017
Received: January 19, 2017

Dear Emmy Tjoeng:

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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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 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 yours,

Michael J. Ryan -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)*
K161099

Device Name
Powder Free Nitrile Examination Gloves, Black

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves, Black 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.

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

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"510 (K)" SUMMARY
K161099

1.0 Submitter

Name of applicant : Prakash
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Phone No. : 62-61-8459170
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Contact person in U.S.A : Emmy Tjoeng
Fax No. : 909-591-8878
Email : emmyt@smcgloves.com

2.0 Name of the Device

Powder Free Nitrile Examination Gloves, Black

Common Name : Nitrile Exam Gloves

Classification Name : Patient Examination Gloves (21 CFR 880.6250)

Product Code : LZA

Date Prepared : February 23, 2017

3.0 Identification of The Legally Marketed Devices That equivalency is claimed:

Primary Predicate:

Chlorinated Powder Free Nitrile Examination Gloves (Black Color)
Company: Worldmed Manufacturing Sdn.Bhd
510(k): K123116
Regulatory Class I
Product Code: LZA.

4.0 Description of the Device:

The proposed device is a Powder Free Nitrile Examination Glove. The glove is available in one color: Black. The proposed device is non-sterile. The Powder Free Nitrile Examination Gloves, Black meets all the requirements of ASTM Specification D6319-10 – Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Indications for Use:

The Powder Free Nitrile Examination Gloves, Black 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.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves, Black are summarized with the following technological characteristics and is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with nitrile and meets ASTM D6319-10 – Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D6319-10: Length –min. 230mm Width –min. 95 ± 10mm	Meets ASTM D6319-10 Standard requirements Minimal value for Length: 240 mm Minimal value for Width: 95mm
Physical Properties	ASTM D6319-10: Tensile Strength: Before Aging: 14 MPa After Aging: 14 MPA Ultimate Elongation: Before Aging: min. 500% After Aging: min. 400%	Meets ASTM D6319-10 Standard requirements Tensile Strength: Before Aging: Minimal Value: 19.05 MPa After Accelerated Aging: Minimal Value: 16.25 MPa Ultimate Elongation: Before Aging Minimal Value: 755% After Aging Minimal Value: 625%
Thickness	ASTM D6319-10 Palm – min 0.05mm Finger – min 0.05mm	Meets standard requirements Standard requirements Palm – min. 0.09mm Finger – min. 0.11mm

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Biocompatibility	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	**Under the condition of the Study – Not an irritant**
	ISO 10993-10:2010 Biological evaluation of medical devices –Part 10: Tests for irritation and skin sensitization	**Under the condition of the Study –Not a sensitizer**
Freedom from Pinholes	21 CFR 800.20; ASTM D5151-06 AQL 2.5	Meets 21 CFR 800.20 and ASTM D5151 –06 Standard Requirements Passes AQL 2.5
Powder Residual	ASTM D6124-06: ≤ 2 mg/ glove	Meets ASTM D6124-06 Standard requirements Minimal Value: 0.45 mg

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as described in Section 6.0 above and meets the following standards:
ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.
ASTM D5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

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8.0 Substantial Equivalence Comparison of K161099

The Powder Free Nitrile Examination Gloves, Black is substantially equivalent to the predicate device with respect to intended use, product features and the technological characteristics. The substantial equivalence comparison is presented in the table below:

Characteristic and Parameters	Chlorinated Powder Free Nitrile Examination Gloves (Black Color) Bhd. K123116 (Predicate)	Powder Free Nitrile Examination Gloves, Black. K161099 (Proposed)	Substantial Equivalence (SE)
Product Code	LZA	LZA	SAME
Intended use	Intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner..	SAME
Indications for Use Statement	The Chlorinated Powder Free Nitrile Examination Gloves (Black Color) is a single use disposable device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient	The Powder Free Nitrile Examination Gloves, Black 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.	SAME
Device Material	Nitrile Synthetic Latex	Nitrile Synthetic Latex	SAME
Color	Black	Black	SAME
Additives	No flavor additive	No flavor additive	SAME
Instruction for Use on Labeling	Single Use Only	Single Use Only	SAME
Construction	Ambidextrous	Ambidextrous	SAME
Sterility	Non-sterile	Non-sterile	SAME
Acceptance Criteria	ASTM D6319-10	ASTM D6319-10	SAME
Device Tolerance & Specifications:			

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Dimensions	Meets ASTM D 6319-10 Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm	Meets ASTM D 6319-10 Overall Length – min. 230mm Width(±5mm) Size XS – 75mm Size S – 85mm Size M – 95mm Size L – 110mm Size XL - 115mm Thickness at Finger – min. 0.05mm Thickness at Palm – min. 0.05mm	SAME
Physical Properties	Meets ASTM D6319-10: **Before Aging** Tensile strength –min. 14.0MPa Ultimate Elongation –min. 500% **After Aging** Tensile Strength – min 14.0MPa Ultimate Elongation –min. 400%	Meets ASTM D6319-10: **Before Aging** Tensile strength –min. 14.0MPa Ultimate Elongation – min. 500% **After Aging** Tensile Strength – min 14.0 MPa Ultimate Elongation – min. 400%	SAME
Biocompatibility Test a. Irritation Tests b. Skin Sensitization Tests	Under the conditions of the study, the subject device is a non-irritant and non-sensitizer. (ISO 10993-10 (2010))	**Under the conditions of the study, the subject device is a non-irritant and non-sensitizer. (ISO 10993-10 (2010))**	SAME
Residual Powder Test	Meets ASTM D6124-06: ≤ 2 mg/ glove	Meets ASTM D6124-06: ≤ 2 mg/ glove	SAME
Freedom from Holes	Meets ASTM D5151-06 AQL 2.5	Meets ASTM D5151-06 Passes AQL 2.5	SAME

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9.0 Conclusion

The Powder Free Nitrile Examination Gloves, Black meet all of the requirements of FDA-recognized consensus standards; ASTM D6319-10, ASTM D5151-06, ASTM D6124-06 and ISO 10993-10:2010 and meet our labeling claims and pinhole acceptable quality level (AQL) as shown above.

There are no significant differences between the subject and predicate devices and the two are similar in terms of intended use, materials, and performance.

The conclusion drawn from the nonclinical tests demonstrate that the device is as safe and as effective and performs as well as the legally marketed device.

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