November 28, 2017

Central Medicare Sdn. Bhd.
Arivalagan Subramaniam
QA/RA Manager
PT 2609 - 2620, BT 8, Jalan Changkat Jong
Teluk Intan, 36000 My

Re: K172642
Trade/Device Name: Orange Non Sterile Powder Free Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: August 25, 2017
Received: September 1, 2017

Dear Arivalagan Subramaniam:

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,

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)*

K172642

Device Name

Orange Non Sterile Powder Free Nitrile Examination Gloves

Indications for Use *(Describe)*

Orange Non Sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand 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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K172642

Section 2 - 510(k) Summary

Date of Summary Prepared: 25th August 2017

1.0 Submitter:

Name: Arivalagan Subramaniam
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Address: Central Medicare Sdn. Bhd.
PT 2609-2620, Batu 8,
Jalan Changkat Jong, 36000 Teluk Intan,
Perak, Malaysia
Contact: Tel: +605-629 0000 Fax: +605-629 0001

510(k) Submission Prepared by: Muhammad Abdul Rahman
Regulatory Affairs Officer
Central Medicare Sdn. Bhd.

2.0 Name of the device:

Orange Non Sterile Powder Free Nitrile Examination Gloves

Common Names: Examination Gloves
Device Class: Class I
Classification Names: Patient Examination Gloves (21 CFR 880.6250 product code LZA)
Review Panel: General Hospital

3.0 Identification of the Legally Marketed Devices that equivalency is claimed:

	Proposed Device	Predicate Device	Remark
Sponsor	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Same**
Trade Name	Orange Non Sterile Powder Free Nitrile Examination Gloves	Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored)	Similar
510k Number		K143247	
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same

4.0 Description of the Device:

Orange Non Sterile Powder Free Nitrile Examination are Class I Patient Examination Gloves. They are ambidextrous, and come in different sizes – Extra Small, Small, Medium, Large and Extra Large. Gloves meet the specification of ASTM D6319-10 and follows the FDA Medical Glove Guidance Manual.

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Section 2 - 510(k) Summary

5.0 Intended Use of the Device:

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.

6.0 Summary of the Technological Characteristics of the Device:

The proposed and predicate devices all share the same technological characteristics and design by meeting ASTM D6319-10 and following the FDA's Medical Glove Guidance Manual.

The purpose of this submission is to demonstrate that the proposed device is substantially equivalent, to a legally marketed predicate device, K143247, Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored). The proposed device will be known as Orange Non Sterile Powder Free Nitrile Examination Glove.

Biocompatibility studies were performed on the proposed device. Under the conditions of the study, the proposed device is not a sensitizer, or an irritant.

The proposed and predicate devices are made of nitrile synthetic latex. The proposed device have similar technological characteristics compared to the predicate devices, as both devices meet ASTM D6319-10 and follow FDA's Medical Glove Guidance Manual.

The technological characteristics and design for the proposed device have been assessed and confirmed that the standard specifications and performance are appropriate for the requirements of a powder free nitrile examination glove.

The following tables are summaries of the technological characteristics of the proposed and predicate devices.

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Section 2 - 510(k) Summary

General Comparison Table:

	Proposed Device	Predicate Device	Remark
Sponsor	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Central Medicare Sdn. Bhd. (as both the sponsor and manufacturer)**	**Same**
Trade Name	Orange Non Sterile Powder Free Nitrile Examination Gloves	Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored)	Similar
510k Number		K143247	
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Orange Non Sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Orange	Blue, Black and White	Similar
Labeling Information	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Single-use indication, powder free, device name, glove size, quantity, Nitrile Examination Gloves, Non Sterile	Same

Dimensions Table:

Proposed Device								
Orange Non Sterile Powder Free Nitrile Examination Gloves		**Size**					**Tolerance**	**Same**
		XS	**S**	**M**	**L**	**XL**		
	Length (mm)	minimum 230						
	Width (mm)	70	80	95	110	120	±0.10	
	Thickness (mm)							
	Palm						-	
	Finger						-	
Predicate Device								
Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored)		**Size**					**Tolerance**	
		XS	**S**	**M**	**L**	**XL**		
	Length (mm)	minimum 230						
	Width (mm)	70	80	95	110	120	±0.10	
	Thickness (mm)							
	Palm						-	
	Finger						-	
Standard Specification								
ASTM D6319 - 10(2015) Standard Specification for Nitrile Examination Gloves for Medical Application		**Size**					**Tolerance**	
		XS	**S**	**M**	**L**	**XL**		
	Length (mm)	minimum 230						
	Width (mm)	70	80	95	110	120	±0.10	
	Thickness (mm)							
	Palm						-	
	Finger						-	

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Section 2 - 510(k) Summary

Performance Comparison Table:

Item			Proposed Device	Predicate Device	Remark
			Orange Non Sterile Powder Free Nitrile Examination Gloves	Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored)	
Color			Orange	Blue, Black and White	Similar
Physical Properties	Before Aging	Tensile Strength	15 Mpa min	15 Mpa min	Same
		Ultimate Elongation	500% min	500% min	Same
	After Aging	Tensile Strength	14 Mpa min	14 Mpa min	Same
		Ultimate Elongation	400% min	400% min	Same
Freedom from Holes			In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-I	In accordance with ASTM D5151-06, following ASTM D6319 AQL 2.5/Inspection Level G-I	Similar
Powder Content			Max. 0.50 mg per glove	Max. 0.40 mg per glove	Similar

Biocompatibility and Labeling:

Item		Proposed Device	Predicate Device	Remark
		Orange Non Sterile Powder Free Nitrile Examination Gloves	Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored)	
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	
Labeling		Meet FDA's Recommendations	Meet FDA's Recommendations	Same

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

The proposed device and it's predicate device share the same intended use, are made of the same material, are within the same minimum specifications of thickness and length by meeting ASTM D6319-10, similar labeling, physical properties, freedom from powder, biocompatibility and water tightness.

The above test results demonstrated that the proposed device complies with the following specification and guidance:

ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application

Section 2 - 510(k) Summary

Guidance for Industry and FDA Staff Medical Glove Guidance Manual (Document issued on January 22, 2008)

The following standards were followed to carry out the testing:
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 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension
ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves
ASTM D573 - 04 Standard Test Method for Rubber—Deterioration in an Air Oven
ISO 10993-10:2010 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
16 CFR 1500.41 - Method of testing primary irritant substances

8.0 Substantial Equivalence Based on Assessment of Clinical Performance Data

Clinical data is not necessary for Class I Patient Examination Glove 510(k) Submissions.

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the proposed device is substantially equivalent to the predicate device Powder Free Nitrile Examination Gloves, Non Sterile, (Blue Colored, Black Colored, and White Colored) (K143247).