DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 18, 2017

UG Global Resources Sdn. Bhd.
% Kenneth Stanton
President
UG Healthcare (USA) Inc.
1565 Sunflower Ave
Costa Mesa, California 92626

Re: K162510
Trade/Device Name: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: June 20, 2017
Received: January 19, 2017

Dear Kenneth Stanton:

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 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,

Mark S. Fellman -S

for

Lori 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)*
K162510

Device Name
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Indications for Use *(Describe)*
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue is a disposable device intended for medical purposes that is worn on the examiner 's hand or finger to prevent contamination between the patient and the 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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SUMMARY

PREMARKET 51O(k) NOTIFICATION
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue
K162510

Submission Applicant:

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Official Correspondent:
Kenneth J. Stanton, President
UG Healthcare (USA) Inc. 1565 Sunflower Avenue Costa Mesa, Ca 92626
Tel: (714)444-2248
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Date: June 8, 2017

Description of the Device: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Trade Name:
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Common Name: Nitrile Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6250)
Class 1: Powder-Free Nitrile examination glove LZA that meets all of the requirements of ASTM 6319-10.

Predicative Devices (K112012):Non-Sterile, Powder-Free, Blue, Nitrile Examination Gloves

Device Description: The subject device of this submission is a Nitrile Examination Glove. The glove is non-sterile and meets the recommendations of ASTM 6319-10 . The device is Blue in color.

Indications for Use: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

SUMMARY

PREMARKET 51O(k) NOTIFICATION
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Summary of Technological Characteristics:
Material: Nitrile Cuff: Beaded Powder Residue: Maximum 2mg/glove

Characteristics	Standards	Device Performance
Dimensions	ASTM D 6319-10	Inspection Level-S-2 AQL4.0
Physical Properties	ASTM D 6319-10	Inspection Level-S-2 AQL4.0
Freedom from Pinholes – Water Tight Test 1000ML	ASTM D 6319-10 ASTM D 5151-06	Inspection Level-G-1 AQL 1.5
Powder-Free Residue-	ASTM D 6319-10 ASTM D 6124-06	Maximum 2mg/glove
Biocompatibility	Dermal Sensitization (as per ISO 10993-10 Primary Skin Irritation Test (as per 16 CFR Part 1500)	Not a contact skin sensitizer Not a primary skin irritant

Packaging: 100 pieces per dispenser box, 10 boxes per case, 1,000 gloves per case

Sizes: XS -XL

Substantial Equivalence Table-

		Color	Material	Biocompatibility Tests	ASTM D3578-05(2015) Tensile Strength (MPa)	ASTM D3578-05(2015) Elongation %
Subject Device K162510		Blue	Nitrile	ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	Before Aging- min 14.0	Before Aging - min. 500
				ISO 10993-10 - Dermal Sensitization Assay - Under the conditions of the study, the device is a non-sensitizer	After Aging - min 14.0	After Aging - min. 400
Predicate Device K112012		Blue	Nitrile	ISO 10993-10 - Dermal Sensitization Assay - Under the conditions of the study, the device is a non-sensitizer	Before Aging- min 14.0	Before Aging- min. 500
				ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	After Aging- min 14.0	After Aging - min. 400

		Dimensions	Waterleak	Powder Content	
Subject Device K162510		Palm Width - 95mm +/-10 Medium size Length: 240mm min Thickness; Min ..05mm Palm and finger	AQL 1.5	Max 2.0mg/glove Avg 1.0mg/glove	
Predicate Device K112012		Palm Width- 95mm +/- 10 Medium size Length : 240mm min Thickness: Min .15mm Palm and Min .17mm finger	AQL 1.5	Max 2.0mg/glove Avg .22mg/glove	

		Sizes	Single Use	Indications for Use
Subject Device K162510		XS-XL	Yes	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
Predicate Device K112012		XS-XL	Yes	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

Comparisons-Both K162510 and K112012 are Non-Sterile, Powder-Free Nitrile Examination Gloves. Both have the same specifications except for thickness, both have the same AQL 1.5 for pinholes and similar powder content. Both gloves have passed the Biocompatibility Test. Additionally, both devices have similar tensile strength and elongation performance.

Conclusion:

This product is as safe, as effective, and performs as well or better than the legally marketed device K112012 (Non-Sterile, Powder-Free Blue, Nitrile Examination Gloves).