DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 11, 2017

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

Re: K161961
Trade/Device Name: UniTex Non-Sterile, Powder-Free, Latex Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 5, 2017
Received: April 7, 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,

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)*
K161961

Device Name
UniTex Non-Sterile, 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 examiners hand or finger to prevent contamination between 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 510(k) NOTIFICATION
UniTex Non-Sterile, Powder-Free, Latex Examination Glove
K161961

Submission Applicant-
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Official Correspondent -

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Date of Preparation: April 13, 2017

Trade Name: UniTex Non Sterile, Powder Free, Latex Examination Glove

Common Name: Latex Examination Gloves

Classification Name: Patient Examination Glove (per 21 CFR 880.6250)
Class 1: Powder-Free Latex examination glove, LYY that meets all of the requirements of ASTM D3578-05(2015).

Predicate Device: K010879,UniGlove Powder-Free Examination Gloves with Protein Content Labeling Claim (50 Micrograms or Less)

Device Description: The subject device of this submission is a natural rubber latex examination glove. The glove is non-sterile and meets the recommendations of ASTM D3578-05(2015). The device is natural in color.

Indications for Use: 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 the patient and the examiner.

Substantial Equivalence Table-

		Color	Material	Biocompatibility Tests	ASTM D3578 Tensile Strength (MPa)	ASTM D3578 Elongation %
Subject Device K161961		Natural	Latex	ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	Before Aging- min 18.0	Before Aging - min. 650
				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. 500
Predicate Device K010879		Natural	Latex	ISO 10993-10 - Dermal Sensitization Assay - Under the conditions of the study, the device is a non-sensitizer	Before Aging- min 21.0	Before Aging- min. 700
				ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	After Aging- min 16.0	After Aging - min. 500

		ASTM D3578 Dimensions	ASTM D5151 Waterleak	ASTM D5712 Protein Claim	ASTM D6124 Powder Content
Subject Device K161961		Palm Width - 95mm +/-10 Medium size Length: 240mm min Thickness; Min . 08mm Palm and finger	AQL 1.5	50 Micrograms or less of total water Soluble Protein per dm^2	Max 2.0mg/glove Avg .06mg/glove
Predicate Device K010879		Palm Width- 95mm +/- 10 Medium size Length: 240 mm min Thickness: Min .15mm Palm and Min .17mm finger	AQL 1.5	50 Micrograms or less	Max 2.0mg/glove Avg .40mg/glove

		Sizes	Single Use	Indications for Use
Subject Device K161961		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 K010879		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 Kl61961 and K010879 are Chlorinated Powder-Free Latex Examination Gloves. Both gloves have protein levels below the 50 Microgram per dm^2 Threshold, 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 tests. Additionally, both devices have similar tensile strength and elongation performance.

Summary of Technological Characteristics:

Material: Latex **Cuff:** Beaded **Powder Residue:** Maximum 2mg/glove

Protein: 50 Micrograms or less of total water soluble protein per dm^2

Quality Assurance: In compliance with ASTM D3578-05, ISO 2859-1:1999, manufactured under ISO 9001:2008, ISO 13485:2003 and EN ISO 13485:2012

Inspection Parameters:

Criteria	Inspection Level	AQL
Dimensions	S-2	4.0
Physical Properties	S-2	4.0
Water Tight Test 1000ml	G-1	1.5
Visual Major Defects	G-1	1.5
Visual Minor Defects	G-1	2.5

Physical Properties:

Dimensions:

Overall Length:	240 mm minimum
Width: Thickness:	95 mm minimum (for medium glove)
	0.08 mm minimum

	BEFORE AGING	AFTER AGING
Tensile Strength:	18.0 Mpa minimum	14.0 Mpa minimum
Ultimate Elongation:	650% minimum	500% minimum

Special Properties: None

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

Sizes: XS-XL

Conclusion: The UniTex Non-Sterile, Powder-Free, Latex Examination Glove meets the physical property requirements of ASTM D3578-05(2015), the FDA 1000 ml water test both before and after aging, and the Protein Labeling Claim Level at 50 Micrograms or less of total water soluble protein per dm^2 controlled during routine production as per ASTM 5712-15. This product is as safe, as effective, and performs as well or better than the legally marketed device cleared under 510(k) # K010879.