February 20, 2018

Jiangsu U-MED Rubber & Plastic Products Co.,Ltd.
% Chu Xiaoan
Official Correspondent
Beijing Easylink CO., LTD
Rm. F302 Bldg., 41, Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang,
Beijing, 100021 CN

Re: K173228
Trade/Device Name: U-MED Powder Free Polyethylene Examination Gloves,Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: September 22, 2017
Received: November 22, 2017

Dear Chu Xiaoan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173228

Device Name

U-MED Powder Free Polyethylene Examination Gloves,Blue Color

Indications for Use *(Describe)*

Powder Free Polyethylene Examination Gloves,Blue Color is a non-sterile 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

"The assigned 510(k) number is: K173228 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Jiangsu U-MED Rubber & Plastic Products Co.,Ltd.
Submitter's address :	Luzhuang Road,Suyu High-Tech Zone,Suqian City,Jiangsu Province,223804,China.
Phone number :	0086-512-81625988
Fax number :	0086-512-58455833
Name of contact person:	Chen Ye
Date of preparation :	2018-01-24

2.0 Name of the Device

Device Name:	U-MED Powder Free Polyethylene Examination Gloves,Blue Color
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LZA

3.0 Predicate device

Device Name:	C2 Powder Free Polyethylene Examination Glove
Company name:	AmerCare Inc.
510(K) Number:	K113639
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA

4.0 Device Description:

The U-MED Powder Free Polyethylene Examination Gloves,Blue Color are non-sterile disposable Patient examination glove. The gloves are made of translucent (clear), Low Density Polyethylene material and are powder free. The U-MED Powder Free Polyethylene Examination Gloves,Blue Color come in four sizes: Small, Medium, Large, X Large.

The Powder Free Polyethylene Examination Gloves, Blue Color acts as a barrier to prevent contamination between patient and examiner. The physical and performance characteristics of the devices meets all requirements of ASTM D5250 and ASTM D5151.

5.0 Indication for use:

Powder Free Polyethylene Examination Gloves, Blue Color is a non-sterile 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 Comparison table:

Features & Description	Predicate Device	Subject Device	Result of Comparison
Company	AmerCare Inc.	Jiangsu U-MED Rubber & Plastic Products Co.,Ltd.	--
510(K) Number	K113639	K173228	--
Product name	Powder Free Polyethylene Examination Glove	U-MED Powder Free Polyethylene Examination Gloves,Blue Color	Similar
Product Code	LZA	LZA	Same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	Same
Indication for use	A powder-free ,no-sterile patient examination gloves is disposable device intended for ,medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Powder Free Polyethylene Examination Gloves,Blue Color 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.	Similar
Device Description and Specifications	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2015)	Same
Dimensions: Overall length, Width, Palm and Finger thickness	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2015)	Same
Physical Properties Tensile Strength before aging/after aging	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2015)	Same
Ultimate Elongation before aging/after aging	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2015)	
Freedom from Pinholes Holes	Holes at Inspection Level I AQL2.5	Holes at Inspection Level I AQL2.5	Same
Residual Powder	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2015)	Same
Materials used to fabricate the devices	Polyethylene	Polyethylene	Same

Color	Translucent [clear]	Blue color	Different
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-06 (Reapproved 2015) ASTM D5250-06 (Reapproved 2015) ASTM D6124-06 (Reaffirmation 2011)	Same
Single Patient Use	Single Patient Use	Single Patient Use	Same
Biocompatibility	Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006	Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10 Third Edition 2010-08-01	Same
Labeling for the legally marketed device to which substantial equivalence is claimed.	There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels. -Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels. -Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	Same

7.0 Summary of the Technological Characteristics of the Device:

Powder Free Polyethylene Examination Gloves, Blue Color are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	**Standard**		
Dimension	ASTM D 5250-06(Reapproved 2015).		
	Length	≥230mm	
	Width	Small	80-90 mm
		Medium	90-100mm
		Large	100-110mm
		X large	110-120 mm
	Thickness	Fingertip	≥0.05mm
		Palm	≥0.08mm
Physical Properties	ASTM D 5250-06(Reapproved 2015).		
	Tensile strength (Before & After aging)		≥11MPa
	Elongated rate (Before & After aging)		≥300%
Freedom from pinholes	• 21 CFR 800.20 • ASTM D5250-06(Reapproved 2015) • ASTM D5151-06(Reapproved 2015)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 5250-06(Reapproved 2015).and D6124-06(Reaffirmation 2011)		Meets <2mg/glove

Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01	Passes Under the conditions of the study, the subject device is not a primary skin irritant.
	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01	Passes Under the conditions of the study, the subject device is not a skin sensitizer.

8.0 Non-Clinical Performance Data:

U-MED Powder Free Polyethylene Examination Gloves,Blue Color, meet requirements per ASTM D5250-06(Reapproved 2015), per ASTM D6124-06 Reaffirmation 2011), per 21 CFR 800.20 and ISO 10993-10:2010-08-01.

Those verification tests of gloves were performed by qualified test centers according to the above standards and included dimensions, Tensile strength (Before & After aging) & Elongated rate (Before & After aging), powder residual, water leak testing, a n d biocompatibility.t. The overall results of the testing demonstrated that the subject glove passed testing performed according to ASTM D5250, Tensile strength (Before & After aging) was demonstrated more than 11MPa, Elongated rate (Before & After aging) was demonstrated more than 300%, powder residual was demonstrated less than 2 mg/device. The subject glove also did not raise any biocompatibility concerns when tested according to ISO 10993-5 and ISO 10993-10.The detail information for the non-clinical testing performed was shown on **section 7.0 Summary of the Technological Characteristics of the Device.**

9.0 Clinical Performance Data:

Clinical performance testing was not needed for this device.

10.0 Conclusion:

Based on the nonclinical tests data, it can be concluded that the U-MED Powder Free Polyethylene Examination Gloves,Blue Color is as safe, as effective, and performs as well as the predicate device, C2 Powder Free Polyethylene Examination Glove AmerCare Inc. K113639.