May 31, 2022

Mastermax Plastic (Huizhou) LTD
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518100
China

Re: K212699
Trade/Device Name: Disposable Powder Free Polyethylene Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 26, 2022
Received: May 2, 2022

Dear Tracy Che:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212699

Device Name
Disposable Powder Free Polyethylene Examination Gloves

Indications for Use *(Describe)*
Disposable Powder Free Polyethylene Examination Gloves are powder free and non-sterile disposable devices intended for medical purposes that are 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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K212699

510k Summary

This 510(k) Summary is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Mastermax Plastic (Huizhou) LTD
Address:	No.1, Qingli 3rd Road, Shuikou, Huicheng district, Huizhou, Guangdong, China
Contact person:	Benson Xu
Phone number:	+86-752-2315076
Email:	Bensonmastermax1@126.com
Date of summary prepared:	2022-5-24

(2) Proprietary name of the device

Trade name/model:	Disposable Powder Free Polyethylene Examination Gloves
Common name:	Polymer Patient Examination Glove
Regulation number:	21 CFR 880.6250
Product code:	LZA
Review panel:	General Hospital
Regulation class:	Class I

(3) Predicate device

Sponsor	Jiangsu U-MED Rubber & Plastic Products Co.,Ltd.
Device Name and Model	U-MED Powder Free Polyethylene Examination Gloves, Blue Color
510(k) Number	K173228
Product Code	LZA
Regulation Number	21 CFR 880.6250
Regulation Class	Class I

(4) Description/ Design of device:

The Disposable Powder Free Polyethylene Examination Gloves are non-sterile disposable patient examination glove. The gloves are made of translucent (clear), low density polyethylene material and are powder free. The Disposable Powder Free Polyethylene Examination Gloves come in four sizes: Small, Medium, Large, X Large.

The Disposable Powder Free Polyethylene Examination Gloves act as a barrier to prevent

contamination between patient and examiner. The physical and performance characteristics of the device meets all requirements of ASTM D5250 and ASTM D5151.

(5) Indications for use:

Disposable Powder Free Polyethylene Examination Gloves are powder free and non-sterile disposable devices intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(6) Technological Characteristics Comparison:

Item	Subject device	Predicate device	Comparison
Company	Mastermax Plastic (Huizhou) LTD	Jiangsu U-MED Rubber & Plastic Products Co.,Ltd	/
Trade name	Disposable Powder Free Polyethylene Examination Gloves	U-MED Powder Free Polyethylene Examination Gloves, Blue Color	/
510 (k) number	K212699	K173228	/
Regulation number	21CFR 880.6250	21 CFR 880.6250	Same
Product code	LZA	LZA	Same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	Same
Class	I	I	Same
Indications for use / Intended use	Disposable Powder Free Polyethylene Examination Gloves are powder free and non-sterile disposable devices intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner.	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.	Similar
Device Description and Specifications	Meets ASTM D5250-19	Meets ASTM D5250-06 (Reapproved 2015)	Similar
Dimensions: Overall length, Width, Palm and Finger thickness	Meets ASTM D5250-19	Meets ASTM D5250-06 (Reapproved 2015)	Similar

Item	Proposed device	Predicate device	Remark
Physical Properties Tensile Strength before aging/after aging	Meets ASTM D5250-19	Meets ASTM D5250-06 (Reapproved 2015)	Similar
Ultimate Elongation before aging/after aging	Meets ASTM D5250-19	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 D5250-19	Meets ASTM D5250-06 (Reapproved 2015)	Similar
Materials used to fabricate the devices	Polyethylene	Polyethylene	Same
Color	Translucent [clear]	Blue color	Different
Performance Data Standard	Meets ASTM D5151-19 ASTM D5250-19 ASTM D6124-06 (Reapproved 2017)	Meets ASTM D5151-06 (Reapproved 2015) ASTM D5250-06 (Reapproved 2015) ASTM D6124-06 (Reaffirmation 2011)	Similar
Single Patient Use	Single Patient Use	Single Patient Use	Same
Biocompatibility	Under the conditions of this study, not have cytotoxicity and Under the conditions of this study, not an irritant and Under the conditions ofthis	Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION	Similar

Item	Proposed device	Predicate device	Remark
	study, not a sensitizer. SKIN IRRITATION and SENSITIZATION STUDIES Meet ISO 10993-10: 2010 In Vitro Cytotoxicity Meets ISO 10993-5: 2009	DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10 Third Edition 2010-08-01	
Labeling	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 -Lot Shelf life of 3 years	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	Similar

(7) Summary of the Technological Characteristics of the Device:

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

Characteristics	Standard		
Dimension	ASTM D 5250-19		
	Length	≥230mm	
	Width	Small	85±5mm
		Medium	95±5mm
		Large	105±5mm
		X large	115±5mm
	Thickness	Finger	≥0.08mm
		Palm	≥0.08mm
Physical Properties	ASTM D 5250-19		
	Tensile strength (Before & After aging)		≥11MPa
	Elongated rate (Before & After aging)		≥300%
Freedom from pinholes	● ASTM D5250-19 ● ASTM D5151-19		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D5250-19 and D6124-06 (Reapproved 2017)		Meets <2mg/glove
Biocompatibility	In Vitro Cytotoxicity MTT method ISO 10993-5: 2009		Pass Under the experimental conditions, the test

		article has no potential toxicity to L-929 in the MTT method.
	Skin Irritation in rabbits ISO 10993-10: 2010	Pass Under the experimental conditions, the test article has no potential skin irritation on rabbit in the extraction method.
	Skin sensitization in the guinea pig ISO 10993-10: 2010	Pass Under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

(8) Non-Clinical Performance Data:

The Disposable Powder Free Polyethylene Examination Gloves meet requirements per ASTM D5250-19, per ASTM D 5151-19, per ASTM D6124-06 (Reapproved 2017), ISO 10993-5: 2009 and ISO 10993-10: 2010.

Those verification tests of gloves were performed by qualified test center according to the above standards and included dimensions, tensile strength (before & after aging) & elongated rate (before & after aging), powder residual, water leak testing, and biocompatibility. The overall results of the testing demonstrated that the subject glove passed testing performed according to ASTM D5250-19. Tensile strength (Before & After aging) was demonstrated as more than 11MPa, elongated rate (before & after aging) was demonstrated as more than 300%, powder residual was demonstrated as less than 2mg/glove. The subject glove also did not raise any biocompatibility concerns when tested according to ISO 10993-5 and ISO 10993-10. The detailed information for the non-clinical testing performed can be seen in corresponding test reports and are summarized as the following table.

Test Method	Purpose	Acceptance criteria	Results
Dimension ASTM D 5250-19	To evaluate the physical dimension of the gloves.	Length: ≥230mm; Width: Small 85±5mm Medium 95±5mm Large 105±5mm X large 115±5mm; Thickness: ≥0.08mm	Pass, the test results meet the acceptance criteria.

		(finger, palm)	
Physical Properties ASTM D 5250-19	To evaluate the physical properties (tensile strength and elongated rate before & after aging).	Before Aging Tensile strength: ≥11MPa Ultimate elongation: ≥300%; After Aging Tensile strength: ≥11MPa Ultimate elongation: ≥300%	Pass, the test results meet the acceptance criteria.
Freedom from pinholes ASTM D5250-19 ASTM D5151-19	Detection of the holes that allow water leakage.	Do not show droplet, stream or other type of water leakage at Inspection Level I AQL2.5	Pass, no leakage.
Powder Residual ASTM D5250-19 ASTM D6124-06 (Reapproved 2017)	To evaluate the residual powder.	Less than 2.0mg/glove	Pass, the test results meet the acceptance criteria.
In vitro cytotoxicity ISO 10993-5	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not have potential toxicity to L-929 in the MTT method.	Pass, the test article has no potential toxicity to L-929 in the MTT method.
Skin sensitization ISO 10993-10	To evaluate the biological safety of the product which has direct contact with intact skin.	The test article should not cause delayed dermal contact sensitization in the guinea pig.	Pass, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article has no potential skin sensitization on guinea pigs in the extraction method.
Skin irritation	To evaluate the	The irritation response	Pass, the response of

ISO 10993-10	biological safety of the product which has direct contact with intact skin.	category in the rabbit should be negligible.	the test article extract was categorized as negligible under the test condition. The test article has no potential skin irritation on rabbit in the extraction method.

(9) Clinical data

Clinical performance testing was not needed for this device.

(10) Conclusion

Based on the nonclinical tests performed, the subject device, Disposable Powder Free Polyethylene Examination Gloves, are as safe, as effective, and perform as well as or better than the legally marketed predicate device, K173228, U-MED Powder Free Polyethylene Examination Gloves, Blue Color.