January 23, 2022

Xuzhou Full Sun Medical Products Ltd.
Elizabeth Deng
U.S. Representative
5748 Eaglewood Place
Rancho Cucamonga, California 91739

Re: K210463
Trade/Device Name: Thermoplastic Elastomer (TPE) Hybrid Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 20, 2021
Received: December 23, 2021

Dear Elizabeth Deng:

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,

For Clarence W. Murray III, PhD
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)*
K210463

Device Name
Thermoplastic Elastomer (TPE) Hybrid Examination Glove

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers 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.

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徐州富山医疗制品有限公司
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TEL：+86-516-67680090 · FAX：+86-516-67680098

510(k) SUMMARY

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K210463

0.0 Summary Preparation Date: Jan. 20th, 2022

1.0 Submitter:

Submitter's name:	Xuzhou Full Sun Medical Products Ltd.
Submitter's address:	Bihe Industry Area, Yitang Town, Pizhou County, Jiangsu, China 221316
Phone number:	86 - 516 - 67680555
Fax number:	86 - 516 - 67680098
Name of contact person:	Hsun-Hui Huang

2.0 US Agent:

US Representative Name:	Elizabeth Deng
Company Address:	5748 Eaglewood Place Rancho Cucamonga, California Rancho Cucamonga, CA 91739
Telephone Number:	909 4659188
Contact Email Address:	baxianunited48@yahoo.com

3.0 Name of the Device

Proprietary/Trade name:	Thermoplastic Elastomer (TPE) Hybrid Examination Glove
Common Name:	Polymer Examination Gloves
Classification Name:	Non-powdered Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA

4.0 Predicate device

Device Name:	Disposable Powder Free Nitrile Examination Glove, Pink/Black Color
Company name:	Ever Growth (Vietnam) Co., Ltd.
510(K) Number:	K190942

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5.0 Device Description:

Thermoplastic Elastomer (TPE) Hybrid Examination Glove is a patient examination glove made from polyethylene resin and styrene-ethylene-butylene-styrene (SEBS) compound, non-sterile (as per 21 CFR 880.6250, Class I). The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

6.0 Device Indications for use:

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

7.0 Comparison of device technological characteristics:

Device / Characteristic	Predicate Device	Subject Device	Comparison
Product Name	Disposable Powder Free Nitrile Examination Glove, Pink/Black Color	Thermoplastic Elastomer (TPE) Hybrid Examination Glove	N/A
510(K) No.	K190942	K210463	N/A
Product Owner	Ever Growth (Vietnam) Co., Ltd.	Xuzhou Full Sun Medical Products Ltd.	N/A
Product Code	LZA	LZA	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Indications for Use	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	Thermoplastic Elastomer (TPE) Hybrid Examination Glove is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	same
Power free	Yes	Yes	same
Size	X Small /Small/ Medium/Large/X Large	Small/Medium/Large/X Large	similar
Single Use	YES	YES	same
Non-Sterile	YES	YES	Same

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Device / Characteristic	Predicate Device	Subject Device	Comparison
Dimensions-Length	Complies with ASTM D6319-10 230 mm min.	Complies with ASTM D6319-19 230 mm min.	same
Dimensions - Palm Width	Complies with ASTM D6319 X Small 70 ± 10 mm Small 80 ± 10 mm Medium 95 ± 10 mm Large 110 ±10 mm X large 120 ±10 mm	Internal Standard Small 104 ± 5 mm Medium 107± 5 mm Large 115 ± 5 mm X large 123 ± 5 mm	Similar. Due to the characteristic of PE material, we use longer dimension for palm width.
Dimensions - Thickness	Complies with ASTM D6319 Palm - 0.05 mm min. Finger - 0.05 mm min.	Complies with ASTM D6319 Palm - 0.05 mm min. Finger - 0.05 mm min.	same
Physical Properties	Tensile Strength Before Aging: 14 MPa, min. After Aging: 14 MPa, min.	Tensile Strength Before Aging: 14 MPa, min. After Aging: 14 MPa, min.	same
	Elongation: Before Aging: 500% min. After Aging: 400% min.	Elongation: Before Aging: 500% min. After Aging: 400% min.	same
Residual powder	Complies with ASTM D6319 ＜ 2mg per glove	Complies with ASTM D6319 ＜ 2mg per glove	same
Freedom from Holes	In accordance with ASTM D6319 and ASTM D5151 (G-1, with AQL 2.5)	In accordance with ASTM D6319 and ASTM D5151 (G-1 with AQL 2.5)	same
Biocompatibility	ISO 10993-10 Skin Sensitization and Skin Irritation test: Passes ISO 10993-5 In vitro cytotoxicity test: Passes	ISO 10993-10 Skin Sensitization and Skin Irritation test: Passes ISO 10993-5 In vitro cytotoxicity test: Passes	same

8.0 Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. Thermoplastic Elastomer (TPE) Hybrid Examination Glove made by Xuzhou Full Sun Medical Products Ltd. met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing:

Test	Test Method	Purpose	Acceptance Criteria	Results
Dimension	ASTM D3767	Determine the geometrical dimension of gloves	Length: 230 mm min. Thickness: Palm - 0.05 mm min. Finger - 0.05 mm min. Palm Width: Small 104 ± 5 mm Medium 107± 5 mm Large 115 ± 5 mm X large 123 ± 5 mm	Pass
Freedom from holes (Water leak)	21 CFR 800.20. & ASTM D5151-19	Detect the holes on the gloves.	G-I/AQL 2.5	Pass
Tensile strength (Before aging/After aging)	ASTM D412-16 & ASTM D573-04	Evaluate the tensile (tenson) properties of the gloves. In addition, it also determines the influence of elevated temperature on the physical properties of gloves.	Before Aging: 14 MPa, min. After Aging: 14 MPa, min.	Pass
Elongation (Before aging/After aging)	ASTM D412-16 & ASTM D573-04		Before Aging: 500% min. After Aging: 400% min.	Pass
Powder Residual	ASTM D6124-06	Determine the average powder mass found on the gloves	＜ 2mg per glove	Pass
Biocompatibility-Skin Irritation	ISO 10993-10:2010	determine the potential of glove to promote skin sensitization & irritation reactions after repeated applications	Negative Response	Pass
Biocompatibility-Skin Sensitization	ISO 10993-10:2010		No contact sensitization	Pass
Biocompatibility-cytotoxicity	ISO 10993-5:2009	determine the cytotoxicity potential of glove	No *in vitro* cytotoxicity	Pass

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9.0 Assessment of Clinical Performance Data:

Clinical data is not needed for this type of device.

10.0 Conclusion:

The conclusion drawn from the nonclinical tests demonstrate that the subject device Thermoplastic Elastomer (TPE) Hybrid Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed device.