January 22, 2023

UR Industry SDN BHD
% A.C. Thirumaran
Official Correspondent
Integrated Assessment Services Pvt Ltd
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Chennai, Tamil Nadu 600040
India

Re: K222531
Trade/Device Name: Synthetic Polymer Glove – Polyethylene (Black)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 31, 2022
Received: January 3, 2023

Dear A.C. Thirumaran:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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)*
K222531

Device Name
Synthetic Polymer Glove - Polyethylene (Black)

Indications for Use *(Describe)*
Powder Free Polyethylene Examination Gloves, 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.

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510(K) Summary

SYNTHETIC POLYMER GLOVE- POLYETHYLENE (BLACK)

Preparation Date: 31/12/2022

510k: K222531

1. **Submitter**:
   Company Name: UR Industry Sdn. Bhd.
   Company Address: NO. 180, Jalan Murni 9, Taman, Perindustrian Murni, 81400 Senai, Johor Darul Takzim, Malaysia.
   Facility Registration Number: 3018161411
   Contact person: Mr. Chua Song Han _ Managing Director

2. **Name of the Device**
   Trade Name / Proprietary Name: Synthetic Polymer Glove- Polyethylene (Black)
   Device Common Name: Polyethylene Examination gloves.
   Device Classification Name: Non-Powdered Patient Examination Glove (21 CFR 880.6250).
   Device Class: Class I.
   Product Code: LZA

2. **Official Correspondent**
   Mr. A.C. Thirumaran
   Integrated Assessment Services Private Limited
   No.1495, Manasarovar, 16th Main Road,
   Anna Nagar west,
   Chennai- 600040,
   India.
   Email: iasfda16@gmail.com

4. **Identification of the Legally Marketed Device (Predicate Device):**
   510K: K210463
   Submitter: Xuzhou Full Sun Medical Products Ltd
   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

5. **Device Description**

The subject device in this 510(k) Notification is Synthetic Polymer- polyethylene - Powder Free Examination Glove. The subject device is a patient examination glove made from Low Density Polyethylene material, Black Color, Powder free and non-sterile (Per 21 CFR 880.6250 - class I). The device meets the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application. The available sizes of the subject devices are Small, Medium, Large, X-Large & XX Large.

6. Intended use of the Device

Powder Free Polyethylene Examination Gloves, 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. It is for over-the-counter use.

7. Technological characteristics Comparison for the proposed and predicate devices

Characteristics	**Acceptance Criteria**	**Subject device: Synthetic Polymer Glove- polyethylene (Black) UR INDUSTRY SD BHD (Small/ Medium/ Large/X large/XX Large) K222531**	**Predicate Device Thermoplastic Elastomer (TPE) Hybrid Examination Glove Xuzhou Full Sun Medical Products Ltd. (Small/ Medium/ Large/X large) K210463**	**Remarks**
Product Code	LZA	LZA	LZA	same
Intended use	A powder free 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. The device is for over- the- counter use.	This powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over- the- counter use.	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 examine	same
Material used	Low Density Polyethylene material	Low Density Polyethylene material	Low Density Polyethylene material	same
Color	N/A	Black	Blue	Different
Sterility	Sterile/Non-sterile	Non sterile	Non sterile	same
Single use	Single use	Single use	Single use	same
Dimensions	Overall Length (mm) Min 230mm	**Avg. value of 13 pcs (mm)** Small - 261.53 Medium- 260.1 Large- 260.08 X-large- 259.8 XX -Large - 268.5	Complies with ASTM D6319-19 230 mm min	same
	Width (±10 mm) Small - 80 Medium- 95 Large-110 X-large-120 XX -Large 130	**Avg. value of 13 pcs (mm)** Small - 86.30 Medium- 99.4 Large-115.23 X-large-123.54 XX -Large 134.5	Small – 104 ± 5 mm Medium- 107 ± 5 mm Large-115 ± 5 mm X-large-123 ± 5 mm	Our product of all ranges meets the ASTM D6319 dimensional requirement. Whereas, the predicate device has exceeded in dimensional requirement of ASTM D6319 and claims to have adhered to their Internal Standard and nature of the material.
	Thickness at Palm (mm) Min; 0.05 mm	Palm - 0.06 mm.	Palm - 0.05 mm min.	same

UR INDUSTRY SDN BHD
Synthetic Polymer Glove- Polyethylene
510k Premarket submission- Traditional

Characteristics	Acceptance Criteria	Subject device: Synthetic Polymer Glove-polyethylene (Black) UR INDUSTRY SD BHD (Small/ Medium/ Large/X large/XX Large) K222531	Predicate Device Thermoplastic Elastomer (TPE) Hybrid Examination Glove Xuzhou Full Sun Medical Products Ltd. (Small/ Medium/ Large/X large) K210463	Remarks
	Thickness at Finger Tip (mm) Min 0.05 mm	Finger - 0.06 mm.	Finger - 0.05 mm min	same
Physical Properties - ASTM D412-16 & ASTM D573-04	Before Ageing – Tensile strength = 14MPa, min.	**Tensile Strength (MPa) Avg. value of 13 pcs** Small - 18.6 Medium -17.45 Large -18.53 X Large -17.4 XX Large 18.69	Tensile Strength 14 MPa, min.	same
	Before Ageing – Ultimate elongation = 500%	**Avg. values of 13 pcs Ultimate elongation (%)** Small - 653.43 Medium - 673.5 Large - 689.15 X Large - 636.56 XX Large - 645.83	Elongation: Before Aging: 500% min.	same
	After Ageing – Tensile strength = 14MPa, min.	**Tensile Strength (MPa) Avg. values of 13 pcs** Small- 17.8 Medium - 18.13 Large - 18.61 X Large - 18.3 XX Large - 18.34	After Aging: 14 MPa, min.	same
	After Ageing – Ultimate elongation = 400%	**Avg. values of 13 pcs Ultimate elongation (%)** Small - 645.18 Medium - 680.2 Large - 686.15 X Large - 614.58 XX Large - 636.87	After Aging: 400% min.	same
Freedom from pinholes ASTM D5151-19	AQL 2.5 Inspection Level G-1	Free from Holes	Free from Holes	same
Residual Powder ASTM D6124-06	< 2.0 mg/pc	＜ 2mg per glove	＜ 2mg per glove	same
Bio- Compatibility	ISO 10993-23:2010 Biological evaluation of medical devices: Tests for irritation	Non-Skin irritant	Non-Skin irritant	same
	ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests For skin sensitization	No contact sensitization	No contact sensitization	same
	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	No Invitro cytotoxicity	No Invitro cytotoxicity	Same

8. Summary of non-clinical testing results

Iconic Nitrile Glove was tested and found in conformance with the following standards:

ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation on medical device Part 10: Test for Skin Sensitization
ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation

Test Methodology	Purpose	Acceptance Criteria	Average Results					Final status
			Small	**Medium**	**Large**	**X Large**	**XX Large**	
ASTM D6319-19	Sterility	-	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile	-
	Freedom from hole - ASTM D5151-19	AQL 2.5	Pass	Pass	Pass	Pass	Pass	Pass
	Dimension - width, Length, Thickness	Overall Length (mm) Min 230mm.	261.53	260.1	260.08	259.8	268.5	Pass
		Width (±10 mm) Small - 80 Medium- 95 Large-110 X-large-120 XX -Large -130	86.30	99.4	115.23	123.54	134.5	Pass
		Thickness at Palm & fingertip Min: 0.05 mm						
		Palm	0.06	0.06	0.06	0.06	0.06	Pass
		Fingertip	0.06	0.06	0.06	0.06	0.06	Pass
	Physical properties before aging, after accelerated aging	**a. Before Aging**						
		Tensile Strength=14 MPa, min.	18.6	17.45	18.53	17.4	18.69	Pass
		Ultimate Elongation= 500% min	653.43	673.5	689.15	636.56	645.83	Pass
		b. After Accelerated Aging						
		Tensile Strength=14 MPa, min.	17.8	18.13	18.61	18.3	18.34	Pass
		Ultimate Elongation= 400 % min	645.18	680.2	686.15	614.58	636.87	Pass
	Powder-free Residue exceeds maximum limit - ASTM D6124-06	< 2.0 mg per glove	Not detected	Not detected	Not detected	Not detected	Not detected	Pass
ISO 10993-5	Test for Invitro cytotoxicity	Non- Cytotoxic	Pass					

ISO 10993-10	Test for irritation and Skin Sensitization	Non - Skin Sensitized	Pass
ISO 10993-23	Tests for irritation	Non-Irritant	Pass

9. Summary of clinical Performance data

Not applicable - Clinical data was not used to assess performance of the subject device.

10. Conclusion

The Conclusion drawn from the non-Clinical test demonstrates that the subject device - Synthetic Polymer Glove- polyethylene (Black) is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K210463.