August 16, 2023

The Egyptian Company For Medical & Electronic Industries
Alaa Elsayed
General Manager
Industrial Zone 7. Part 7062A&B
Sadat City, Monofeya
Egypt

Re: K230832
Trade/Device Name: Powdered Free Sterile Natural Rubber Latex Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: July 14, 2023
Received: July 14, 2023

Dear Alaa Elsayed:

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,

Allan Guan -S

For 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)*
K230832

Device Name
Powdered Free Sterile Natural Rubber Latex Surgical Gloves

Indications for Use *(Describe)*
The powdered free sterile natural rubber latex surgical gloves is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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 (K230832)

(As required by 21 CFR 807.92)

I. SUBMITTER INFORMATION

Egyptian company for medical & electronic industries EMI
Address: Sadat City-Industrial Zone7.Part 7062A&B-Monofeya, Egypt
Phone: +201000080166
Email: alaa.elsayed@emiegypt.com
Type of 510(k) Submission: traditional

Contact person: Alaa Elsayed
Email: alaa.elsayed@emiegypt.com
Tel: + 201000080166
Date updated: 16/08/2023

II. DEVICE

Name of Device: Powdered Free Sterile Natural Rubber Latex Surgical Gloves
Regulation medical specialty: general and plastic surgery
Review panel: general hospital
Common or Usual Name: Non-powdered surgeon's glove
Classification Name: Non-powdered surgeon's glove.
Product Code: KGO
Regulation number: 21CFR 878.4460
Device Class: I
510(k) Number: K230832

III. PREDICATE DEVICE

510(k) Number: K211953
Clearing date: 25/05/2022
Product Name: Disposable Sterilized Latex Surgical Gloves
Submitter: Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd
Product Code: KGO
Regulation number: 21CFR 878.4460
Device Class: I

IV. DEVICE DESCRIPTION

The device is a sterile, single-use, non-pyrogenic, latex surgical glove.

The proposed device is made of natural rubber latex. Per standard ASTM D3577-09(15), the rubber surgical gloves classification is: "Type 1-gloves compounded primarily from natural rubber latex." The proposed device is provided EO sterilized to achieve the sterility Assurance Level (SAL) of 10^{-6}.

The gloves are powdered free and available in four sizes 7, 7.5, 8, 8.5 to be suitable for user's hand.

The Glove palm has textured surface.

V. INDICATIONS FOR USE

The powdered free sterile natural rubber latex surgical gloves is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Subject device	Predicate device (K211953)	Discussion
Device name	Powdered Free Sterile Natural Rubber Latex Surgical Gloves	Disposable sterilized latex surgical gloves	-
Manufacturer	Egyptian company for medical & electronic industries EMI	Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd	-
Device classification name	surgeon's gloves	surgeon's gloves	Same
FDA regulation number	21 CFR 878.4460	21 CFR 878.4460	Same
Classification Product Code	KGO	KGO	Same
FDA classification	I	I	Same
Regulation medical specialty	General& plastic surgery	General& plastic surgery	Same
Classification as per ASTMD3577-09, Standard Specification for Rubber Surgical Glove	Type 1 - gloves compounded primarily from natural rubber latex,	Type 1 - gloves compounded primarily from natural rubber latex,	Same
510k review panel	General hospital	General hospital	Same
FDA identification	A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing	A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing	Same
Description	Sterile Powder free, surgical gloves are made of natural Rubber latex. The gloves are provided in Sizes 7.0, 7.5, 8.0 and 8.5	A non-powdered surgeon's glove is made of natural rubber latex, per standard ASTM D3577-09(15), the rubber surgical gloves classification is: “Type 1-gloves compounded primarily from nature rubber latex.” The gloves are powder-free and available in white in sizes 6, 6.5, .7, 7.5, 8, and 8.5	The sizes within the Range of the predicate device
Material	Natural rubber	Natural rubber	Same

Indications for use statement	The powdered free sterile natural rubber latex surgical gloves are device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	The Disposable Sterilized Latex Surgical Glove is a device made of nature rubber intended to be worn by operating room personnel to protect a surgical wound from contamination	Same
Powdered/ powdered free	Powdered free	Powdered free	Same
Color	Natural (no color is added)	White	Same
Sizes	7, 7.5, 8 and 8.5	6, 6.5, 7, 7.5, 8 and 8.5	The sizes within the range of the predicate device
Dimensions	Length: Size 7: 265 mm, min Size 7.5: 265 mm, min Size 8: 265 mm, min Size 8.5: 265 mm, min	Length: Size 6: 265mm, min Size 6.5: 265mm, min Size 7: 265mm, min Size 7.5: 265mm, min Size 8: 265mm, min Size 8.5: 265mm, min	Same Meeting requirement of ASTM D 3577
	Width: Size 7: 89 ± 6 mm Size 7.5:95 ± 6 mm Size 8: 102 ± 6 mm Size 8.5: 108 ± 6 mm	Width: Size 6: 76 ±6 mm Size 6.5: 83 ± 6 mm Size 7: 89 ± 6 mm Size 7.5: 95 ± 6 mm Size 8: 102 ± 6 mm Size 8.5: 108 ± 6 mm	
	Palm thickness: 0.10 mm, min Finger thickness: 0.10 mm, min Cuff thickness:0.10 mm, min	Palm Thickness: 0.10mm, min Finger Thickness: 0.10mm, min Cuff Thickness: 0.10mm, min	
Single use	Yes	Yes	Same
Type of use	Over the counter use	Over the counter use	Same
Label and Labeling	Meet FDA's Requirement	Meet FDA's Requirement	Same

Packaging	Packed 1 pair in a wallet. One wallet in a pouch.		Packed 1 pair in a wallet. One wallet in a pouch.		Same
Sterile or non-sterile	Sterile		Sterile		Same
Sterilization	ETO, SAL- 10^{-6}		ETO, SAL- 10^{-6}		same
Shelf life	5 years		3 years		Different
Pyrogenic or / non pyrogenic	Non pyrogenic		Non pyrogenic		Same
Material-mediated pyrogenicity	No temperature rise ≥0.5°C		No temperature rise ≥0.5°C		Similar[1]
Bacterial endotoxin	<20EU/device		<20EU/device		Same
Sensitization	Non-sensitizer		Non-sensitizer		Same
Irritation	Non-irritant		Non-irritant		Same
Acute systemic toxicity	No evidence of acute systemic toxicity.		No evidence of acute systemic toxicity.		Same
Hemolytic property	Non-hemolytic		N/A		Different
Tensile strength	Before Aging	24MPa, min	Before Aging	24MPa, min	Same
	After Aging	18MPa, min	After Aging	18MPa, min	
Ultimate Elongation	Before Aging	750%, min	Before Aging	750%, min	Same
	After Aging	560%, min	After Aging	560%, min	
Freedom from holes	Meets ASTM D5151-06(2015) AQL 1.5		Meets ASTM D5151-06(2015) AQL 1.5		Same
Protein Content	Meets ASTM D5712-15(2020)		Meets ASTM D5712-15(2020)		Same
Powdered residue	Meets ASTM D6124-06 (Reapproved 2017)		Meets ASTM D6124-06 (Reapproved 2017)		Same
EtO and ECH residuals	Meets ISO 10993-7:2008		Meets ISO 10993-7:2008		Same

[1]The subject device was tested for material-mediated pyrogenicity per the Japanese Pharmacopeia Rabbit Pyrogen Test whereas the predicate was tested using USP<151>. However, testing was equivalent.

VII. SUMMARY OF NONCLINICAL PERFORMANCE TESTING

The gloves were tested according to the following standards:

- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D3577-19 Standard Specification for Rubber Surgical Gloves
- ASTM D5712-15 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method
- ISO 10993-1:2018 Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- USP 43 <85> Bacterial Endotoxin Test
- Japanese Pharmacopeia Rabbit Pyrogen Test
- ANSI/AAMI/ISO 10993-4:2017: Hemolysis testing

Test method	standard	Test procedure	Criteria	Result
Dimension	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To determine the length of the gloves	265mm, min	**pass**
	ASTM D3577-09(Reapproved 2015)Standard Specification for Rubber Surgical Gloves	To determine the width of the gloves	Size 7: 89 ± 6 mm Size 7.5: 95 ± 6 mm Size 8: 102 ± 6 mm Size 8.5: 108 ± 6 mm	**pass**
	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To determine the thickness of the gloves	Palm: 0.10mm, min Finger: 0.10 mm, min Cuff: 0.10mm, min	**pass**
Physical Properties	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To Determine the physical properties Tensile strength	**Before Ageing** Tensile Strength 24Mpa Minimum for all sizes **After Ageing** Tensile Strength 18Mpa Minimum for all sizes	**pass**
	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To Determine the physical properties Ultimate Elongation	**Before Ageing** Ultimate Elongation 750% Min for all sizes **After Ageing** Ultimate Elongation 560% Min for all sizes	**pass**
	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To Determine the physical properties stress at 500 %	5.5 Mpa, Max	**pass**
Watertight test	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the water tightness of the test gloves	AQL 1.5	**pass**
Residual powder	ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 mg per glove or less	**pass**
Protein content	ASTM D5712 - 15, Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber.	To determine the extractable protein in the gloves.	50 µg/ dm^2 Max for all sizes	**pass**

Skin Sensitization	ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation	The test was designed to evaluate the potential of a test article to cause skin sensitization.	Under the conditions of the study, not a sensitizer	**pass**
Irritation	ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation	To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits.	Under the condition of study, not an irritant	**pass**
Acute Systemic toxicity	ISO 10993-11:2017 biological evaluation of medical devices - part 11, tests for systemic toxicity	The test article was evaluated to determine whether leachable extracted from the test article would cause acute systemic toxicity following injection into mice.	Under the conditions of study, the device extracts do not pose an acute systemic toxicity concern	**pass**
Material mediated pyrogenicity	Japanese Pharmacopeia Rabbit Pyrogen Test	The test article was evaluated to determine the risk of febrile reaction in rabbits following intravenous injection.	Under the conditions of the study, non- pyrogenic	**pass**
Hemolysis test	ANSI/AAMI/ISO 10993-4:2017	The test article was assessed to determine whether the test article would cause hemolysis in vitro by direct contact method.	Under the conditions of the study, non-hemolytic	**pass**
Bacterial Endotoxin	USP 43 <85> Bacterial Endotoxin Test	Bacterial Endotoxin Test	<20 EU/ pair of gloves	**pass**
EO Residue	ISO 10993-7:2008	Determine if the Ethylene Oxide residues of test article is within the requirements.	Not more than 4mg/device	**pass**
ECH Residue	ISO 10993-7:2008	Ethylene Chlorohydrin level determination	Not more than 9mg/device	**pass**

VIII. SUMMARY OF CLINICAL TESTING

No clinical testing is included in this submission.

IX. CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the subject device, powdered Free Sterile Natural Rubber Latex Surgical Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K211953.