May 25, 2022

Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd
% Alice Huang
RA Manager
Shanghai Mind-Link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K211953
Trade/Device Name: Disposable Sterilized 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: April 15, 2022
Received: April 25, 2022

Dear Alice Huang:

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, M.D., Ph.D.
Acting 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)*
K211953

Device Name
Disposable Sterilized Latex Surgical Gloves

Indications for Use *(Describe)*
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.

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

K211953

I. SUBMITTER:

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Summary prepared：05/23/2022

II. DEVICE

510(k) Number: K211953
Name of Device: Disposable Sterilized Latex Surgical Gloves
Regulation Number: 21 CFR878.4460
Common Name: Surgeon's Gloves
Classification Name: Non-powdered surgeon's glove
Regulatory Class: I
Product Code: KGO

III. PREDICATE DEVICE

510(k) Number: K171550
Product Name: Sterile Latex Surgical Gloves, Powder Free
Manufacture: Sanrea Healthcare Pvt Ltd

IV. DEVICE DESCRIPTION

The proposed device, Disposable Sterilized Latex Surgical Gloves is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

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 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 proposed device is provided EO sterilized to achieve the sterility Assurance Level (SAL) of 10^{-6}. The disposable sterilized latex surgical glove shelf life is 3 years.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Disposable Sterilized Latex Surgical Gloves are compared with the predicate device (Sterile Latex Surgical Gloves, Powder Free, K171550). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	**Subject Device**	**Primary Predicate Device (K171550)**	**Comparison**
Indications For Use	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.	The Sterile Latex Surgical Gloves, Powder free, is a disposable device made of natural rubber, intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.	Same

Intended Use	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.		Intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.		Same
Classification Product Code	KGO		KGO		Same
Regulation No.	21 CFR 878.4460		21 CFR 878.4460		Same
Class	I		I		Same
Powdered or Powdered free	Powdered free		Powdered free		Same
Material	Natural Rubber Latex		Natural Rubber Latex		Same
Dimensions	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		size 7.5 : Length : 300mm		Similar Meeting requirement ASTM D 3577
	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		size 7.5 : Width : 95mm		Similar Meeting requirement of ASTM D 3577
	Palm Thickness: 0.10mm, min Finger Thickness: 0.10mm, min Cuff Thickness: 0.10mm, min		Palm Thickness: 0.19mm Finger Thickness: 0.22mm Cuff Thickness: 0.14mm		Similar Meeting requirement of ASTM D 3577
Biocompatibility	Under the conditions of the study, not a sensitizer. Under the conditions of the study, not an irritant. Under the conditions of the study, no evidence of acute systemic toxicity.		Non-sensitizing Non-irritating		Similar
Tensile strength	Before Aging	24MPa, min	Before Aging	31.22MPa	Similar Meeting requirement of ASTM D 3577
	After Aging	18MPa, min	After Aging	24.43MPa	
Ultimate Elongation	Before Aging	750%, min	Before Aging	843.09%	
	After Aging	560%,min	After Aging	762.28%	
Freedom from	Meets ASTM D5151-06(2015)		Meets ASTM D 5151 -06		Same

Holes	AQL 1.5	(2011)	
Protein Content	Meets ASTM D5712-2015	Meets ASTM D5712	Same
Powdered residue	Meets ASTM D6124-06(Reapproved 2017)	Meets ASTM D 6124-06(2011)	Same
Sterility	EO	EO	Same
EtO and ECH residuals	Meets ISO 10993-7:2008	Meets ISO 10993-7:2008	Same
Shelf life	3 Years	3 Years	Same
Single Use	YES	YES	Same
Label and labeling	Meet FDA's Requirement	Meet FDA's Requirement	Same

VII. SUMMARY OF NON-CLINICAL TESTING

The gloves have the same technological characteristics compared to ASTM or equivalent standards as given below:

- ASTM D5151-06(Reapproved 2015) 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 D3577-09 (Reapproved 2015) 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 : 2009 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
- USP 43-NF 38<151> Pyrogen Test
- USP 43<85> Bacterial Endotoxin Test
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

- ASTM D7160 Standard Practice for Determination of Expiration Dating for medical Gloves

Test Method	Standard	Test Purpose	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 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	Pass
	ASTM D3577-09(Reapproved 2015) Standard Specification for Rubber Surgical Gloves	To determine the thickness of the gloves	Palm: 0.10mm, min Finger: 0.10mm, 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 Minimal for all sizes **After Ageing** Tensile Strength 18Mpa Minimal 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
Watertight test	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the watertightness of the test gloves	Sample size: 200 pcs Inspection level : GI AQL 1.5 Criteria:≤8 pieces	Pass
Residual powder	ASTM D6124-06 (Reapproved 2017) Standard Test Method for	To determine the residual powder in the	2 mg per glove or less	Pass

	Residual Powder on Medical Gloves	gloves		
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.	200 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
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 leachables 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 a systemic toxicity concern	Pass
Pyrogen	USP 43-NF 38<151> Pyrogen Test	The test article was evaluated for the risks of febrile reaction in the rabbit to the administration by injection.	Under the condition of study not a pyrogen	Pass
Bacterial Endotoxin	USP 43 <85> Bacterial EndotoxinTest	Bacterial EndotoxinTest	<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.	≤10ug/cm^2	Pass
ECH Residue	ISO 10993-7:2008	Determine if the Ethylene Chlorohydrin	≤5mg/cm^2	Pass

		residues of test article is within the requirements.		

VIII. SUMMARY OF CLINICAL TESTING

No clinical testing is included in this submission.

IX. CONCLUSION

The conclusions drawn from the non-clinical performance data demonstrate that the subject device, Disposable Sterilized Latex Surgical Glove, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K171550.