July 14, 2022

Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd
℅ Alice Huang
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room 8208, Second Floor, No 1399, Jiangyue Road
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Shanghai, 201114
China

Re: K214017
Trade/Device Name: Examination gloves-Type A(Latex gloves)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: June 14, 2022
Received: June 21, 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)*

K214017

Device Name

Examination gloves-Type A（Latex gloves）

Indications for Use *(Describe)*

The Examination gloves-Type A（Latex gloves） 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.

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
K214017

I. SUBMITTER:

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Summary prepared：07/12/2022

II. DEVICE

Name of Device: Examination gloves-Type A（Latex gloves） Regulation Number: 21 CFR 880.6250
Common Name: Latex patient examination glove Classification Name: Non-powdered patient examination glove Regulatory Class: I
Product Code: LYY

III. PREDICATE DEVICE 510(k) Number: K173053
Product Name: Powder Free Latex Examination Glove Manufacture: Professional Latex Sdn Bhd

IV. DEVICE DESCRIPTION

The proposed device, The Examination gloves-Type A（Latex gloves）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 proposed device is made of natural rubber latex and meet all the current specifications listed under the ASTM Specification D3578-19, Standard Specification for Rubber Examination Gloves. The principal operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is provided non-sterile and the shelf life is 5 years.

V. INDICATIONS FOR USE

The Examination gloves-Type A（Latex gloves） 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device,

DEVICE	Subject Device (K214017)	Primary Predicate Device (K173053)	Comparison
Intended Use	The Examination gloves-Type A（Latex gloves） 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.	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner’s hand or finger to prevent contamination between patient and examiner	Same
Classification Product Code	LYY	LYY	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	Class I	Class I	Same
Powdered or	Powdered free	Powdered free	Same

Powdered free					
Material	Natural Rubber Latex		Natural Rubber Latex		Same
Color	No colour pigment added. Natural White		No colour pigment added. Natural White		Same
Dimensions	Length: S: 240-244mm M：241-245mm L：242-245mm		Length: Average:242mm		Similar Meeting requirement of ASTM D 3578
	Width： S: 84-86mm M：96-98mm L：105-108mm		Width: Average: S:85mm M:95mm L:104mm		
	Palm Thickness：0.11-0.13mm Finger Thickness: 0.13-014mm		Palm Thickness：Average:0.09 Finger Thickness:Average:0.11		
Biocompatibility	Non-sensitizing Non-irritating Non-systemic toxicity		Non-sensitizing Non-irritating		Similar Meeting requirement of ISO 10993
Tensile strength	Before Aging	20.6MPa, min	Before Aging	23.65MPa	Similar Meeting requirement of ASTM D 3578
	Stress at 500 % Elongation	5.1Mpa, max	Stress at 500 % Elongation	3.5MPa	
	After Aging	18.9MPa, min	After Aging	20.99MPa	
Ultimate Elongation	Before Aging	683%, min	Before Aging	734%	
	After Aging	623%,min	After Aging	622%	
Freedom from Holes	Meets ASTM D5151-19		Meets ASTM D5151-19		Same
Protein Content	Meets ASTM D5712-2015		Meets ASTM D5712-2015		Same
Powdered residue	Meets ASTM D6124-06(Reapproved 2017)		Meets ASTM D6124-06(Reapproved 2017)		Same
Sterility	Non-sterile		Non-sterile		Same
Single Use	YES		YES		Same
Label and labeling	Meet FDA's Requirement		Meet FDA's Requirement		Same

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TEST DATA

Test item	Test standard	Acceptance Criteria	Test result	Conclusion
Dimension	ASTM D3578-19	**Length:** Min 230 mm for all sizes	**Length:** S:240-244mm M:241-245mm	Pass

			L:242-245mm	
	ASTM D3578-19	**Width:** Small: 80 ± 10 mm Medium: 95±10mm Large: 111± 10 mm	**Width：** S: 84-86mm M:96-98mm L:105-108mm	Pass
	ASTM D3578-19	**Thickness**: Palm: 0.08 mm min Finger: 0.08 mm min	**Thickness：** Palm:0.11-0.13mm Finger: 0.13-014mm	Pass
Physical Properties-Tensile strength	ASTM D3578-19	**Before Ageing** Tensile Strength: 18Mpa Minimal for all sizes After Ageing Tensile Strength 14Mpa Minimal for all sizes	**Before Ageing** Tensile Strength: 20.6Mpa Min After Ageing Tensile Strength 18.9Mpa Min	Pass
Physical Properties-Ultimate Elongation	ASTM D3578-19	**Before Ageing** Ultimate Elongation: 650% Min for all sizes **After Ageing** Ultimate Elongation 500% Min for all sizes	**Before Ageing** Ultimate Elongation: 683% Min **After Ageing** Ultimate Elongation 623% Min	Pass
Watertight test	ASTM D5151-19	Sample size: 200 pcs Inspection level : GI AQL 1.5 Acceptance Number 7 Rejection Number 8	Sample size: 200 pcs Inspection level : GI AQL 1.5 Result:0	Pass
Residual powder	ASTM D6124-06	2 mg per glove or less	0.02mg per glove	Pass
Protein content	ASTM D5712 - 15	200 µg/ dm^2 Max for all sizes	75ug/g	Pass
Skin Sensitization	ISO 10993-10	Under the conditions of the study not a sensitizer	Non-sensitizing	Pass
Irritation	ISO 10993-10	Under the condition of study not an irritant	Non-irritating	Pass
Systemic toxicity	ISO 10993-11:2017	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Non-systemic toxicity	Pass

- 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 D3578-19 Standard Specification for Rubber Examination 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
- ASTM D7160 Standard Practice for Determination of Expiration Dating for medical Gloves
- ASTM D7161 Standard Practice for Determination of Expiration Date of Medical Gloves
- 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
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 5: Tests For systemic toxicity
- ISO 15233-1-2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

VIII. CONCLUSION

The Conclusion drawn from the Non-Clinical test demonstrates that the subject device, Examination gloves-Type A（Latex gloves） is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K173053.