Guangdong Kingfa Sci.&Tech. Co., Ltd.
℅ Xiaoge Yu
Manager
Guangdong Kingfa Sci.& Tech.Co., Ltd.
No.28, Delong Ave., Shijiao Town, Qingcheng District
Qingyuan, Guangdong 511545
China

Re: K222612
Trade/Device Name: Powder-Free Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: August 12, 2022
Received: August 30, 2022

Dear Xiaoge Yu:

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,

Ramesh C. Panguluri -S
Digitally signed by Ramesh C. Panguluri -S
Date: 2022.11.25 15:19:07 -05'00'

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)*
K222612

Device Name
Powder-Free Latex Examination Gloves

Indications for Use *(Describe)*
The powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger 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
K222612

I. Submitter

GUANGDONG KINGFA SCI. & TECH.CO., LTD.
No.28, Delong Ave., Shijiao Town, Qingcheng District, Qingyuan, Guangdong, China
Contact person: Xiaoge Yu
Position: Manager
Tel.: +86-13570952157
E-mail: yuxiaoge@kingfa.com.cn
Preparation date: November 21, 2022

II. Proposed Device

Device Trade Name	Powder-Free Latex Examination Gloves
Common name:	Latex Patient Examination Gloves
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LYY
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K214017
Trade name:	Examination gloves-Type A (Latex gloves)
Common name:	Latex Patient Examination Gloves
Classification:	Class I
Product Code:	LYY
Manufacturer	Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd

IV. Device description

The proposed device is Powder-Free Latex Examination Gloves. The gloves are single use and are provided non-sterile. 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 proposed device is provided with natural color. The device is available in two lengths, each with six sizes, extra-small (XS), small (S), medium (M), large (L) and extra-large (XL), and extra extra-large (XXL). The device is non-sterile.

V. Indication for use

The powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger or finger to prevent contamination between patient and examiner.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Latex examination gloves

Item	Proposed device	Predicate device (K214017)	Discussion
Product name	Powder-Free Latex Examination Gloves	Examination gloves-Type A (Latex gloves)	-
Product Code	LYY	LYY	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Classification	Class I	Class I	Same
Powder free	Yes	Yes	Same
Indication for use	The powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger or finger to prevent contamination between patient and examiner.	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.	Similar
Main Material	Natural rubber latex	Natural rubber latex	Same
Color	Natural color	Natural White color	Similar
Size	X-Small, Small, Medium, Large, X-large, XX-large,	Small, Medium, Large	Similar
Palm width	X- Small(70±10mm) Small (80±10mm) Medium (95±10mm) Large (110±10mm) X-large (120±10mm)	Small (84-86mm) Medium (96-98mm) Large (105-108mm)	Similar

	XX-large (130±10mm)		
Length	Short style XS(220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min) Long style XS~XXL(280mm min)	≥230mm	Similar
Thickness	Palm: 0.05mm min Finger: 0.08mm min	Palm: 0.11-0.13mm Finger:0.13-0.14mm	Similar
Freedom from holes	Meets requirements of ASTM D3578-19	Meets requirements of the ASTM D3578-19	Same
Physical Properties (before aging)	Meets requirements of ASTM D3578-19	Meets requirements of ASTM D3578-19	Same
Physical Properties (after aging)	Meets requirements of ASTM D3578-19	Meets requirements of ASTM D3578-19	Same
Powder residue	Meets requirements of ASTM D3578-19	Meets requirements of ASTM D3578-19	Same
Protein Content	Meets requirements of ASTM D3578-19	Meets requirements of ASTM D3578-19	Same
Sterility	Non-sterile	Non-sterile	Same
Shelf Life	-	5 Years	Different
For single use	Yes	Yes	Same
Type of use	Over the counter use	Over the counter use	Same
Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Same

As above comparison, the differences in the dimensions of the subject and predicate device do not affect the safety and effectiveness of the device for its intended use. The biocompatibility test and performance test of the subject devices have been performed on the final finished device.

VII. Non-Clinical Testing

Non clinical tests were conducted in accordance with following standards to verify that the subject device (short and long variants) met all design specifications.

Test	Purpose	Criteria	Result
ASTM D3578-19 Tensile properties	Demonstrate adequate tensile strength (unaged)	Greater than 18 MPa	Pass
	Demonstrate adequate elasticity at 500% elongation (unaged)	Stress less than 5.5 MPa	Pass
	Demonstrate adequate ultimate elongation (unaged)	Greater than 650%	Pass
	Demonstrate adequate tensile strength after aging	Greater than 14 MPa	Pass
	Demonstrate adequate ultimate elongation after aging	Greater than 500%	Pass
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	Demonstrate glove integrity	AQL 2.5	Pass
ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves	Demonstrate low powder	Less than 2.0 mg/glove	Pass
ASTM D5712-15, Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber	Demonstrate low level of extractable protein	protein content not more than 200 μg/ dm^2	Pass

in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method			
ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.	Demonstrate low potential for skin irritation	Under the conditions of the testing, not an irritant	Pass
	Demonstrate low potential for skin sensitizer	Under the conditions of the testing, not a sensitizer	Pass
ISO 10993-11:2017, Biological evaluation of medical devices – Part 11:Tests for Systemic Toxicity	Demonstrate low acute systemic toxicity	Under the conditions of the testing of the testing, no acute systemic toxicity	Pass

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the Powder-Free Latex Examination Gloves are as safe, as effective, and perform as well as or better than the predicate Examination gloves-Type A (Latex gloves) (K214017).