March 25, 2023

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

Re: K230046
Trade/Device Name: Vinyl examination gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: December 28, 2022
Received: January 6, 2023

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,

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)*
K230046

Device Name
Vinyl examination gloves

Indications for Use *(Describe)*

The vinyl examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

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

K230046

I. Submitter

GUANGDONG KINGFA SCI. & TECH.CO., LTD.
No. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province 511545, China

Contact person: Xiaoge Yu
Position: Manager
Tel.: +86-13570952157
E-mail: yuxiaoge@kingfa.com.cn Prepa

Date: March 2, 2023

II. Proposed Device

Device Trade Name	Vinyl examination gloves
Common name:	Vinyl Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LYZ
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K213006
Trade name:	Vinyl examination gloves
Common name:	Vinyl Patient Examination Glove
Classification:	Class I
Product Code:	LYZ
Manufacturer	Taian Hengchang Medical Technology Co.,Ltd.

IV. Device description

The proposed device is a powder free vinyl patient examination glove, provided as non-sterile and disposable device. The proposed device is provided with clear color. There are four sizes: small, medium, large and extra-large as options.

V. Indication for use

The vinyl examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Vinyl Examination Gloves

Item	Proposed device K230046	Predicate device (K213006)	Discussion
Product name	Vinyl examination gloves	Vinyl examination gloves	-
Product Code	LYZ	LYZ	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 vinyl examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.	The vinyl examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Main Material	Vinyl	Vinyl	Same
Color	Clear	Clear	Same
Size	Small, Medium, Large, X-large	Small, Medium, Large, X-large	Same
Palm width	Small (85±5mm) Medium (95±5mm) Large (105±5mm) X-large (115±5mm)	Small (85±5mm) Medium (95±5mm) Large (105±5mm) X-large (115±5mm)	Same
Length	≥230mm	≥230mm	Same
Thickness	Palm: 0.08mm min Finger: 0.08mm min	Palm≥0.08mm Finger tip≥0.08mm	Same

Freedom from holes	Meets requirements of the ASTM D5250-19	Meets requirements of the ASTM D5250-19	Same
Physical Properties (before aging)	Meets requirements of the ASTM D5250-19	Meets requirements of the ASTM D5250-19	Same
Physical Properties (after aging)	Meets requirements of the ASTM D5250-19	Meets requirements of the ASTM D5250-19	Same
Powder residual	≤2.0 mg/gloves	≤2.0 mg/gloves	Same
Sterility	Non-sterile	Non-sterile	Same
For single use	Yes	Yes	Same
Type of use	Over the counter use	Over the counter use	Same
Biocompatibility	ISO 10993-10 Under the conditions of the study, not an irritant and sensitizer ISO 10993-11 Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity *in vivo*. Cytotoxicity is assessed via rationale.	ISO 10993-10 Under the conditions of the study, not an irritant and sensitizer ISO 10993-11 Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity *in vivo* Cytotoxicity is assessed via rationale.	Same

VII. Non-Clinical Testing

Non-clinical tests were conducted in accordance with following standards to verify that the proposed device met all design specifications.

- ASTM D5250-19, Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- 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

Acute Systemic Toxicity.

Table 2 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria			Results
ASTM D5250	Physical Dimensions Test	Length：≥ 230mm Width: Small: 85±5mm; Medium: 95±5mm Large: 105±5mm Extra- Large: 115±5mm			Pass
		Thickness (mm): Finger:≥0.08 Palm: ≥0.08			Pass
	Physical properties	Before Aging	Tensile Strength	≥11MPa	Pass
			Ultimate Elongation	≥300%	
		After Aging	Tensile Strength	≥11MPa	Pass
			Ultimate Elongation	≥300%	
ASTM D5151	Freedom from pinholes	Meet the ASTM requirements D5151 Test for AQL 2.5			Pass
ASTM D6124	Powder Residue	Meet ASTM requirements D6124< 2.0mg			Pass
ISO 10993-10	To determine if the finished device material is an irritant	Non-irritating			Under the conditions of the study, not an irritant. / Pass
ISO 10993-10	To determine if the finished device material is a sensitizer	Non- sensitizing			Under conditions of the study, not a sensitizer. / Pass

ISO 10993-11	To determine if the finished device material extracts pose a systemic toxic response.	Non-acute systemic toxicity	Under conditions of the study, did not show acute systemic toxicity *in vivo*. /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 Vinyl Examination Gloves are as safe, as effective, and perform as well as or better than the predicate, K213006.