September 24, 2022

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

Re: K221887
Trade/Device Name: Nitrile Examination Glove, Pink Color; Nitrile Examination Glove, Black Color, Nitrile Examination Glove, White Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA,
Dated: June 9, 2022
Received: June 29, 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,

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)*
K221887

Device Name
Nitrile Examination Glove, Pink Color
Nitrile Examination Glove, Black Color
Nitrile Examination Glove, White Color

Indications for Use *(Describe)*
The nitrile 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.

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K221887-510(k) summary

I. Submitter

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Contact person: Xiaoge Yu
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Preparation date: June 09, 2022

II. Proposed Device

Device Trade Name	Nitrile Examination Glove, Pink Color Nitrile Examination Glove, Black Color Nitrile Examination Glove, White Color
Common name:	Polymer Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LZA
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K190942
Trade name:	Disposable Powder Free Nitrile Examination Glove, Pink/Black Color
Common name:	Patient Examination Gloves
Classification:	Class I
Product Code:	LZA
Manufacturer	Ever Growth (Vietnam) Co. Ltd.

IV. Device description

The propose devices is powder free nitrile patient examination gloves, provided as non-sterile and disposable device. The proposed devices are provided with white，black and pink color. There are six sizes, extra-small, small, medium, large and extra-large, extra extra-large for optional.

V. Indication for use

The nitrile 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 Nitrile Examination Gloves

Item	Proposed device	Predicate device (K190942)	Discussion
Product name	Nitrile Examination Glove, Pink Color Nitrile Examination Glove, Black Color Nitrile Examination Glove, White Color	Disposable Powder Free Nitrile Examination Glove, Pink/Black Color	-
Product Code	LZA	LZA	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 nitrile 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 Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	Same
Main Material	Nitrile rubber	Nitrile rubber	Same
Color	Pink\ Black\ White	Pink\ Black	Similar
Size	X-Small, Small, Medium, Large, X-large, XX-large,	X-Small, Small, Medium, Large, X-large	Similar

Palm width	X- Small(70±10mm) Small (80±10mm) Medium (95±10mm) Large (110±10mm) X-large (120±10mm) XX-large (≧120mm)	X- Small(70±10mm) Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	Similar
Length	XS(220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min)	≥230mm	Similar
Thickness	Palm: 0.05mm min Finger: 0.08mm min	Palm≥0.05mm Finger tip≥0.05mm	Similar
Freedom from holes	Meets requirements of the ASTM D6319-19	Meets requirements of the ASTM D6319-10	Similar
Physical Properties (before aging)	Meets requirements of the ASTM D6319-19	Meets requirements of the ASTM D6319-10	Similar
Physical Properties (after aging)	Meets requirements of the ASTM D6319-19	Meets requirements of the ASTM D6319-10	Similar
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 Cytotoxicity is assessed via rationale. Under the condition of acute systemic toxicity test, the test article did not	ISO 10993-10 Under the conditions of the study, not an irritant and sensitizer	Same

	show acute systemic toxicity *in vivo*.		

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 D6319-19, Standard Specification for Nitrile Examination 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
- ASTM D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- 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 - Part11:Tests for Systemic Toxicity

Table 2 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Extra-Small: Length：≥ 220mm Width: 70±10 mm; Small: Length：≥ 220mm Width: 80±10mm; Medium: Length：≥ 230mm Width: 95±10mm Large: Length：≥ 230mm Width: 110±10mm Extra- Large: Length：≥ 230mm Width: 120±10mm Extra- Extra- Large: Length：≥ 230mm Width: ≥120mm	Pass X-Small: Length：226 mm Width: 73 mm; Small: Length：225 mm Width: 85 mm; Medium: Length：235 mm Width: 98 mm; Large: Length：234 mm

					Width: 115 mm; X- Large: Length：235 mm Width: 123 mm; XX-Large: Length：235 mm Width: 124 mm;
		Thickness (mm): Finger:≥0.08 Palm: ≥0.05			Pass X-Small: Finger：0.104 mm Palm: 0.059 mm; Small: Finger：0.106 mm Palm: 0.060 mm; Medium: Finger：0.104 mm Palm: 0.060 mm; Large: Finger：0.105 mm Palm: 0.062 mm; X- Large: Finger：0.106 mm Palm: 0.061mm; XX-Large: Finger：0.105 mm Palm: 0.058 mm;
	Physical properties	Before Aging	Tensile Strength	≥14MPa	Pass Lot1:17.6MPa，552% Lot2:18.5MPa，573% Lot3:18.2MPa，583%
			Ultimate Elongation	≥500%	
		After Aging	Tensile Strength	≥14MPa	Pass

			Ultimate Elongation	≥500%	Lot1:19.8MPa，521% Lot2:20.3MPa，518% Lot3:20.1MPa，526%
ASTM D5151	Freedom from pinholes	Meet the requirements of ASTM D5151Test for AQL 2.5			Pass Lot1: ≤ AQL 2.5 Lot2: ≤ AQL 2.5 Lot3: ≤ AQL 2.5
ASTM D6124	Powder Residue	Meet the requirements of ASTM D6124< 2.0mg			Pass Lot1: 1.2 mg Lot2: 1.5 mg Lot3: 1.2 mg
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 toxicity concern	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 nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.