October 28, 2021

Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd
% Evan Hu
Marketing Manager
Shanghai Mind-link Consulting Co., Ltd.
639 Jiaozhou Road
Shanghai, Shanghai 200040
China

Re: K212290
Trade/Device Name: Examination gloves -Type C (Nitrile gloves)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 26, 2021
Received: July 30, 2021

Dear Evan Hu:

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.

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Sincerely,

Clarence W. Murray III -S

Clarence W. Murray, III, 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)*

K212290

Device Name
Examination gloves-Type C（Nitrile gloves）

Indications for Use *(Describe)*

The Examination gloves-Type C (Nitrile 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5.

510(k) Summary – K212290

1. Submitter

Manufacturer: Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.
Address: No. 316 National road, Xinju, Changshan Town, Jinxian County, Nanchang City, 331724 Jiangxi Province, China.
Contact person: Jenny Huang, 86-17702094798, 3454867077@qq.com
Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net, 639 Jiaozhou Road, Shanghai, 200040, China

2. Device

Trading name: Examination gloves – Type C (Nitrile gloves)
Common name: Nitrile patient examination glove
Classification name: Polymer patient examination glove
Classification: Class I
Product code: LZA

3. Predicate device

Primary device: Powder Free Nitrile Examination Glove (Aqua Green) (K200326)

4. Device description

The proposed device is one kind of patient examination glove made from nitrile rubber compounds. The typical characters of these examination gloves are blue color, single-layer, powder-free, non-sterilized, single-use, variable size (see table 2.). These examination gloves can be worn on the examiner's hands or fingers during a medical examination. In addition, it is for over-the-counter use and also for adult use only.
The product specifications are shown in Table 1.

Table 1. Gloves specifications

Size	S	M	L	XL
Length, mm	≥220	≥230	≥230	≥230
Width, mm	80±10	90±10	100±10	≥110
Thickness of Palm*, mm	0.080	0.080	0.080	0.080
Thickness of Finger*, mm	0.150	0.150	0.150	0.150

*The minimum thickness of palm and finger

5. Indication for use

The Examination Gloves-Type C (Nitrile 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.

6. Technological Characteristic Comparison between proposed and predicate devices

Table 2. Characteristics comparison

Characters	Proposed device (K212290)	Predicate device (K200326)	Comparison
Product code	LZA	LZA	Same
Intended use/ Indications for Use	The Examination Gloves-Type C (Nitrile 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 powder free patient examination glove 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 device is for over- the- counter use.	Same
Prescription or over-the-counter use	Over-the-counter use	Over-the-counter use	Same
Material	Nitrile compound	Nitrile compound	Same
Color	Blue	Aqua green	Different
Sterility	Non-sterilized	Non-sterilized	Same
Single-use	Single-use	Single-use	Same
Dimensions	Size S, M, L, XL, meet ASTM D6319-19	Size S, M, L, XL, meet ASTM D6319-10	Same
Physical properties	Before and after aging properties, meet ASTM D6319-19	Before and after aging properties, meet ASTM D6319-10	Same
Freedom from pinholes	Meets ASTM D5151- 19, AQL 2.5	Meets ASTM D5151- 06, AQL 2.5	Same
Residual powder	Meets ASTM D6124- 06, <2mg/glove	Meets ASTM D6124- 06, <2mg/glove	Same
Biocompatibility	Non-irritant, meet ISO 10993-10	Non-irritant, meet ISO 10993-10	Same
	Non-sensitizing, meet ISO 10993-10	Non-sensitizing, meet ISO 10993-10	Same
	Non-cytotoxic, meet ISO 10993-11	Non-cytotoxic, meet ISO 10993-11	Same

7. Summary of Non-Clinical Testing

The non-clinical tests of this proposed device are tested in conformance with the following standards:

(a) ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves

(b) ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
(c) ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
(d) ASTM D412-16, Standards test method for Vulcanized Rubber and Thermoplastics Elastomer – Tension
(e) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization
(f) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity
(g) ISO 28590:2017, Sampling Procedure for Inspection by Attributes
(h) ASTM D7160-16, Standard Practice for Determination of Expiration Dating for Medical Gloves
(i) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

The performance and biocompatibility testing results are shown in Table 3.

Table 3. A summary of the performance/biocompatibility testing results.

Standard	Test Description	Acceptance criteria	Results
ASTM D5151-19	Freedom from holes	No water leakage (0 pinhole)	0 pinhole found
ASTM D6319-19	Physical Dimension	Multi acceptance criteria refer to ASTM D6319 Clause 7.4- TABLE 2.	Meet requirements. Refer to Table 4 below.
ASTM D6319-19, physical requirements	Tensile strength	Multi acceptance criteria refer to ASTM D6319 Clause 7.5- TABLE 3.	Meet requirements. Refer to Table 5 below.
ASTM D6124-06	Residual powder	≤2.0 mg/glove	0.10mg/glove (before aging) 0.12mg/glove (after aging)
ISO 10993-10:2010	Skin sensitization and irritation	No irritation and skin sensitization	No irritation and skin sensitization
ISO 10993-11:2017	Systemic toxicity	No acute systemic toxicity	No acute systemic toxicity

Table 4. Gloves size testing before and after aging, according to ASTM D6319

Size	S	M	L	XL
Before aging				
Length, mm	240	241	246	250
Width, mm	86	95	104	114
Minimum thickness of Palm, mm	0.086	0.087	0.087	0.087
Minimum thickness of Finger, mm	0.150	0.150	0.150	0.150

After aging at 60 °C for 158 days				
Length, mm	240	241	246	250
Width, mm	86	95	104	114
Minimum thickness of Palm, mm	0.086	0.087	0.087	0.087
Minimum thickness of Finger, mm	0.150	0.150	0.150	0.150

Table 5. Gloves physical properties, pinhole testing results, and residual powder, before and after aging.

Size	S	M	L	XL
Before aging				
Tensile strength (MPa)	32	33	33	34
Elongation at break (%)	566	574	576	585
After aging at 60 °C for 158 days				
Tensile strength (MPa)	32	33	32	34
Elongation at break (%)	545	556	561	564

Clinical testing data is not applicable in this case.

8. Conclusion

The conclusions drawn from the non-clinical testing results demonstrates that the proposed device, Examination gloves – Type C (Nitrile gloves), is as safe, as effective and performs as well as or better than the legally marketed predicate device that cleared under K200326.

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.

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Sincerely,

Bifeng Qian -S

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