March 19, 2021

Guang Dong Kingfa SCI. & TECH.CO., LTD.
% Shelley Li
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 703, 705, Baohua International Plaza, West Guangzhong
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Shanghai, 200071
China

Re: K203593
Trade/Device Name: Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 6, 2021
Received: February 16, 2021

Dear Shelley Li:

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,

Ryan Ortega 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
Unknown

Device Name
Nitrile examination gloves

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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510(k) Summary: K203593

I. Submitter

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Preparation date: Mar. 18, 2021

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II. Proposed Device

Device Trade Name	Nitrile examination gloves
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:	K181106
Trade name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Common name:	Patient Examination Gloves
Classification:	Class I
Product Code:	LZA
Manufacturer	JiangSu Dongxin Medical Technology Co., Ltd.

IV. Device description

The propose devices is powder free nitrile examination gloves, provided as non-sterile

and disposable device. The proposed devices are blue color and there are four sizes, includes small (7"), medium (8"), large (8.5"), X-large (9") for optional. The gloves are provided with blue color. The examination glove is smooth surface with textured fingertips and a rolled rim at the cuff edge.
The gloves are manufactured in accordance with the requirements of ASTM D6319-19 and Medical Glove Guidance Manual.

V. Indication for use

The nitrile examination glove is intended to be worn on the hands of examiners 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 Natural Rubber Surgical Gloves

Item	Proposed device (K203593)	Predicate device (K181106)	Discussion
Product name	Nitrile Examination Gloves	Powder Free Nitrile Patient Examination Gloves, Blue 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 examiners to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.	Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Main Material	Nitrile rubber	Nitrile rubber	Same
Color	Blue	Blue	Similar*

Size	Small, Medium, Large, X large	Small, Medium, Large, X large	Same
Palm width	Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	Small (76-90mm) Medium (89-102mm) Large (108-119mm) X large (115-128mm)	Similar Minor difference of palm width does not affect the intended use
Length	S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	232 mm min for all size	Similar The length of the subject device is shorter than the predicate's
Thickness	Palm: 0.05mm min Finger: 0.05mm min	Palm: 0.08mm Finger tip: 0.08mm	Similar The thickness of the subject device is thinner than the predicates
Freedom from holes	Meets requirements of the ASTM D6319-19	Meets requirements of the ASTM D6319-10	Similar Only the different standard version. This requirement given in the standard is the same.
Physical Properties (before aging)	Meets requirements of the ASTM D6319-19 Tensile Strength: ≥14 MPa Elongation: ≥500%	Meets requirements of the ASTM D6319-10 Tensile Strength: ≥14 MPa Elongation: ≥500%	Similar Only the different standard version. The requirements of physical properties given in the standard are the same.

Physical Properties (after aging)	Meets requirements of the ASTM D6319-19 Tensile Strength: ≥14 MPa Elongation: ≥400%	Meets requirements of the ASTM D6319-10 Tensile Strength: ≥14 MPa Elongation: ≥400%	Similar Only the different standard version. The requirements of physical properties given in the standard are the 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
Shelf-life	3 years	Unknown	The shelf-life testing was performed that demonstrate meet the claimed shelf-life.
Biocompatibility - Skin Sensitization Test	Under the test condition of study not a sensitizer	Under the test condition of study not a sensitizer	Same
Biocompatibility - Skin Irritation Test	Under the test condition of study not an irritant	Under the test condition of study not an irritant	Same
Biocompatibility - Cytotoxicity Test	Cytotoxicity is assessed via rationale. Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity *in vivo*.	Under the test conditions, the test article was non-cytotoxic to L-929 cells.	Different

*As above comparison, the difference in the dimensions and reference standard version of the subject and predicate device does not raise additional questions for

safety and effectiveness of the device. The biocompatibility test and performance test of the subject devices have been performed on the final finished device. The test results pass the requirements.

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, Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Test Method for Residual Powder on Medical Gloves
- ASTM D573-04(2019), Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, 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 - Part 11: Tests for systemic toxicity

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K203593, the Nitrile Patient Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K181106.