October 12, 2021

Fitone Latex Products Co., Ltd. Guangdong
% Stuart Situ
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza, 555 West Guangzho
Shanghai, 200072
China

Re: K211927
Trade/Device Name: Nitrile examination gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 7, 2021
Received: September 7, 2021

Dear Stuart Situ:

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,

For Clarence W. Murray, III, PhD
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)*
K211927

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Submitter

Fitone Latex Products Co., Ltd. Guangdong
No.5 Huitong road, Lingbei Industrial Zone, Suixi, 524338 Zhanjiang, Guangdong, China

Contact person: Christine Ou
Position: Manager
Tel.: 0759-7905808
E-mail: market-intl@fitonelatex.com

Preparation date: Jun.11, 2021

US Agent

Qihui Zhang
ZYPPEL LLC
1337 Massachusetts Avenue #158 Arlington
MA, MA US 02476

II. Proposed Device

Device Trade Name	Nitrile examination gloves
Model	NG100
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:	K203593
Trade name:	Nitrile examination gloves
Common name:	Polymer Patient Examination Glove
Classification:	Class I
Product Code:	LZA
Manufacturer	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.

IV. Device description

The propose device (Mode: NG100) is powder free nitrile examination gloves, provided as non-sterile and disposable device. The proposed devices are blue color and there are five sizes, includes XS (6.5"), S (7"), M (8"), L (8.5"), XL (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 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	Standard	Proposed device (K211927)	Predicate device (K203593)	Discussion
Product name	/	Nitrile Examination Gloves	Nitrile Examination Gloves	-
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 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.	Same
Main Material	/	Nitrile rubber	Nitrile rubber	Same
Color	/	Blue	Blue	Similar*

Size	/	X-small, Small, Medium, Large, X large	Small, Medium, Large, X large	Similar Dimensions meet ASTM D6319-19
Palm width	ASTM D6319-19	XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm)	Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	Similar Dimensions meet ASTM D6319-19
Length	ASTM D6319-19	XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	Similar Dimensions meet ASTM D6319-19
Thickness	ASTM D6319-19	Palm: 0.05mm min Finger: 0.05mm min	Palm: 0.05mm min Finger: 0.05mm min	Same
Freedom from holes	ASTM D5151-06	The gloves shall be free from hole when tested in accordance with the method given in ASTM D5151	The gloves shall be free from hole when tested in accordance with the method given in ASTM D5151	Same
Physical Properties (before aging)	ASTM D6319-19	Tensile Strength: 14MPa, min Ultimate Elongation：500% min	Tensile Strength: 14MPa, min Ultimate Elongation：500% min	Same
Physical Properties (after aging)	ASTM D6319-19	Tensile Strength: 14MPa, min Ultimate Elongation：400% min	Tensile Strength: 14MPa, min Ultimate Elongation：400% min	Same
Powder residual	ASTM D6124	≤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	3 years	The shelf-life testing was

				performed that demonstrate meet the claimed shelf-life.
Biocompatibility - Skin Sensitization Test	ISO 10993-10	Under the test condition of study not an sensitizer	Under the test condition of study not an sensitizer	Same
Biocompatibility - Skin Irritation Test	ISO 10993-10	Under the test condition of study not an irritant	Under the test condition of study not an irritant	Same
Biocompatibility - Cytotoxicity Test	ISO 10993-5	Under the test conditions, the test article was non-cytotoxic to L-929 cells.	Cytotoxicity is assessed via rationale. Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	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 shows 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 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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, 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 K203593.