December 1, 2022

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

Re: K221747
Trade/Device Name: Nitrile Patient Examination Gloves Tested For Use With Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: November 2, 2022
Received: November 2, 2022

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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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)*
K221747

Device Name
Nitrile Patient Examination Gloves Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*
The nitrile examination glove is intended to be worn on the examiner's hand to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019)Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Tested chemotherapy drugs are as follows:
Carboplatin, 10 mg/ml >240 min.
Carmustine (BCNU), 3.3 mg/ml 27.5 min
Cisplatin, 1.0 mg/ml >240 min
Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min
Doxorubicin HCI, 2.0 mg/ml >240 min
Etoposide, 20.0 mg/ml >240 min
Fluorouracil, 50.0 mg/ml >240 min
Paclitaxel, 6.0 mg/ml >240 min
Thio Tepa, 10.0 mg/ml 88.2 min

Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3 mg/ml 27.5 Minutes; Thio Tepa 10.0 mg/ml 88.2 Minutes.
Warning: Please do not use with Carmustine and Thio Tepa.

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.

510(k) Summary
K221747

I. Submitter

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Preparation date: Dec.1 2022

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II. Proposed Device

Device Trade Name:	Nitrile Patient Examination Gloves Tested For Use With Chemotherapy Drugs
Model:	NG101
Common name:	Patient Examination Glove (Tested For Use With Chemotherapy Drugs)
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LZA, LZC, OPJ
Review Panel:	General Hospital

III. Predicate Devices

510(k) Number:	K211220
Trade name:	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs
Common name:	Patient Examination Glove (Tested For Use With Chemotherapy Drugs)
Classification:	Class I
Product Code:	LZA, LZC, OPJ
Manufacturer	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.

IV. Device description

The proposed device (Mode: NG101) is powder free nitrile examination gloves, provided as non-sterile and disposable device. The proposed devices are blue color and there are five sizes, include XS (6.5"), S (7"), M (8"), L (8.5"), XL (9") for optional. The examination glove is smooth surface with textured fingertips and a rolled rim at the cuff edge. This is a single-use, powder-free, non-sterile device.
The gloves are designed and manufactured in accordance with the ASTM D6319-10 standard and are tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019)

V. Indication for use

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

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Carboplatin, 10 mg/ml >240 min.

Carmustine (BCNU), 3.3 mg/ml 27.5 min

Cisplatin, 1.0 mg/ml >240 min

Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min

Doxorubicin HCl, 2.0 mg/ml >240 min

Etoposide, 20.0 mg/ml >240 min

Fluorouracil, 50.0 mg/ml >240 min

Paclitaxel, 6.0 mg/ml >240 min

Thio Tepa, 10.0 mg/ml 88.2 min

- Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3 mg/ml 27.5 Minutes; Thio Tepa 10.0 mg/ml 88.2 Minutes.
- Warning: Please do not use with Carmustine and Thio Tepa.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Nitrile Patient Examination Gloves

Item	Proposed device (K221747)	Predicate device (K211220)	Discussion
Product name	Nitrile Patient Examination Gloves Tested For Use With Chemotherapy Drugs	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs	-
Product Code	LZA, LZC, OPJ	LZA, LZC, OPJ	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 a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves of Permeation by Chemotherapy Drugs	Similar[1]
Main	Powder-Free Nitrile	Powder-Free Nitrile	Same

Material			
Color	Blue	Blue	Same
Size	X-small, Small, Medium, Large, X large	small, medium, large, x-large	Similar[2]
Dimensions – Length	Complies with ASTM D6319-19 XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	Complies with ASTM D6319-19 S (220mm min) M (230mm min) L (230mm min) XL (230mm min)	Similar[2]
Dimensions – Width	Complies with ASTM D6319-19 XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm)	Complies with ASTM D6319-19 Small (80±10mm) Medium (95±10mm) Large (110±10mm) X large (120±10mm)	Similar[2]
Dimensions – Thickness	Complies with: ASTM D6319-19 Palm: 0.05mm min Finger: 0.08mm min	Complies with: ASTM D6319-19 Palm: 0.05mm min Finger: 0.11mm min	Similar[2]
Physical Properties	Complies with: ASTM D6319-19 minimum: Tensile Strength: Before Aging ⩾ 14 MPa, min. After Aging ⩾ 14 MPa, min.	Complies with: ASTM D6319-19 minimum: Tensile Strength: Before Aging ⩾14 MPa, min. After Aging ⩾ 14 MPa, min.	Same
	Elongation: Before Aging 500%, min. After Aging 400%, min.	Elongation: Before Aging 500%, min. After Aging 400%, min.	Same
Freedom from Holes	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
Powder or Powder-Free	Powder-Free	Powder-Free	Same
Residual Powder	Complies with: ASTM D6319-19 <2mg per glove	Complies with: ASTM D6319-19 <2mg per glove	Same
Surface	Smooth surface with textured fingertips	Smooth surface	Similar[3]

Contact Durations	Limited <24 hours	Limited <24 hours	Same
Biocompatibility	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer	Same
	AAMI/ANSI/ISO 10993-5: The test article was non-cytotoxic to L-929 cells	AAMI/ANSI/ISO 10993-5: At the neat extraction, the test article is considered cytotoxic	Different[4]
	/	The acute systemic toxicity results demonstrate the device will not cause a systemic effect	Different[4]
Sterility	Non-sterile	Non-sterile	Same
Rx Only or OTC	Over the Counter	Over the Counter	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D6978	Carboplatin, 10 mg/ml >240 min. Carmustine (BCNU), 3.3 mg/ml 27.5 min Cisplatin, 1.0 mg/ml >240 min Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min Doxorubicin HCl, 2.0 mg/ml >240 min Etoposide, 20.0 mg/ml >240 min Fluorouracil, 50.0 mg/ml >240 min Paclitaxel, 6.0 mg/ml >240 min Thio Tepa, 10.0 mg/ml 88.2 min	Carmustine (BCNU) 3.3 mg/ml 65.3 minutes Cisplatin 1.0 mg/ml >240 minutes Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 minutes Dacarbazine (DTIC)10.0 mg/ml >240 minutes Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes Etoposide (Toposar) 20.0 mg/ml >240 minutes Fluorouracil 50.0 mg/ml >240 minutes Paclitaxel (Taxol) 6.0 mg/ml >240 minutes Thiotepa 10.0 mg/ml 58.3minutes	Similar

[1]Except the device name, the contents of indications for use are identical.

[2]As above comparison, the difference in the dimensions between the subject and predicate devices does not raise additional questions for safety and effectiveness of the device.

[3]The surface of the fingertips of the proposed device and predicate device is different. Fingers of the proposed device are textured. However, the thickness or other performance of the proposed device complies with ASTM D6319-19. Therefore, the difference does not raise additional questions for safety and effectiveness of the device.

[4]The Cytotoxicity test result of proposed device and predicate device is different. The test result of proposed device showed no cytotoxic potential to L929 mouse fibroblast cells. Acute systemic toxicity test is not necessary for the proposed device.

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 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
- 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.
- ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Test Methodology	Tested sample	Purpose	Acceptance Criteria	Results
ASTM D6319-19	Final finished product	Physical Dimension	The actual measured dimension of the gloves shall be meet the stated tolerance specified in Table	Meet the requirement

			2 of the ASTM D 6319-19	
ASTM D6319-19	Final finished product	Determination of Physical Properties	Before and after accelerated aging, the gloves shall conform to the physical requirements in the Table 3 of ASTM 6319-19)	Meet the requirement
ASTM D5151-19	Final finished product	Water Leak Test for Detection of Holes	The gloves shall be free from hole when tested in accordance with the method given in ASTM D5151 - 19 AQL =2.5	Meet the requirement
ASTM D6124-06(2017)	Final finished product	Residual Powder Content Test	The powder residue content shall be not more than 2mg per gloves.	Meet the requirement
ISO 10993-5: 2009	Final finished product	In Vitro Cytotoxicity	The MEM test extract shows no cytotoxic potential to L929 mouse fibroblast cells.	Meet the requirement
ISO 10993-10: 2010	Final finished product	Skin Sensitization	The test article extracts show no evidence of causing delayed dermal contact sensitization in the guinea pig.	Meet the requirement
ISO 10993-10: 2010	Final finished product	Skin irritation	There is no erythema and no edema observed on the skin of the animals treated with the test extracts	Meet the requirement

ASTM D6978-05	Final finished product	Chemotherapy Drugs	Carboplatin, 10 mg/ml >240 min. Carmustine (BCNU), 3.3 mg/ml 27.5 min Cisplatin, 1.0 mg/ml >240 min Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min Doxorubicin HCl, 2.0 mg/ml >240 min Etoposide, 20.0 mg/ml >240 min Fluorouracil, 50.0 mg/ml >240 min Paclitaxel, 6.0 mg/ml >240 min Thio Tepa, 10.0 mg/ml 88.2 min	Except for Carmustine and Thio Tepa, acceptance criteria were met.

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 this 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 K211220.