September 24, 2022

Fitone Latex Products Co., Ltd. Guangdong
℅ Stuart Situ
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room1308,Baohua International Plaza,West Guangzhong Road 555
Jingan District
Shanghai, 200072
China

Re: K222693
Trade/Device Name: Single-use medical latex examination gloves (LG100)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: August 30, 2022
Received: September 6, 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.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.

Submission Number *(if known)*

K222693

Device Name

Single-use medical latex examination gloves (LG100)

Indications for Use *(Describe)*

The Single-use medical latex examination 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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510(k) Summary - K222693

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
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date: September 20, 2022

Submission Correspondent

Ms. Stuart Situ
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: stuart.situ@landlink-healthcare.com

US Agent

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

II. Proposed Device

Device Trade Name:	Single-use medical latex examination gloves
Model:	LG100
Common name:	Latex Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LYY
Review Panel:	General Hospital

III. Predicate Devices

510(k) Number:	K214017
Trade name:	Examination gloves-Type A (Latex gloves)
Common name:	Latex Patient Examination Glove

Classification:	Class I
Product Code:	LYY
Manufacturer	Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.

IV. Device description

The proposed device, The Single-use medical latex examination 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.

The proposed device is made of natural rubber latex and meet all the current specifications listed under the ASTM Specification D3578-19, Standard Specification for Rubber Examination Gloves. The principal operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is provided non-sterile, in sizes XS, S, M, L and XL, natural white color, powder free, and the shelf life is 3 years.

V. Indication for use

The Single-use medical latex examination 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.

VI. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison of Single-use medical latex examination gloves

Item	Proposed device (K222693)	Predicate device (K214017)	Discussion
Product name	Single-use medical latex examination gloves	Examination gloves-Type A(Latex gloves)	-
Indications For Use	The Single-use medical latex examination 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.	The Examination gloves-Type A (Latex 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.	Same
Product Code	LYY	LYY	Same

Regulation No.	21 CFR 880.6250		21 CFR 880.6250		Same
Class	I		I		Same
Powdered or Powdered free	Powdered free		Powdered free		Same
Material	Natural Rubber Latex		Natural Rubber Latex		Same
Color	No colour pigment added. Natural White		No colour pigment added. Natural White		Same
Dimensions	Length: 6(XS): 238-241 mm $6^1/_2$(S):240-245mm $7^1/_2$(M): 240-245mm $8^1/_2$(L):246-250mm 9(XL): 246-252mm		Length: S: 240-244mm M：241-245mm L：242-245mm		Similar Meeting requirement of ASTM D 3578
	Width： 6(XS): 74-76 mm $6^1/_2$ (S):80-84mm $7^1/_2$ (M): 94-97mm $8^1/_2$ (L): 105-108mm 9(XL): 114-120mm		Width： S: 84-86mm M：96-98mm L：105-108mm		Similar Meeting requirement of ASTM D 3578
	Palm Thickness：0.11-0.13mm Finger Thickness: 0.13-0.16mm		Palm Thickness：0.11-0.13mm Finger Thickness: 0.13-0.14mm		Similar Meeting requirement of ASTM D 3578
Biocompatibility	Non-sensitizing Non-irritating Non-systemic toxicity		Non-sensitizing Non-irritating Non-systemic toxicity		Same
Tensile strength	Before Aging	24.4 MPa, min	Before Aging	20.6MPa, min	Similar Meeting requirement of ASTM D
	Stress at 500 % Elongation	4.2 Mpa, max	Stress at 500 % Elongation	5.1Mpa, max	

	After Aging	20.5 MPa, min	After Aging	18.9MPa, min	3578
Ultimate Elongation	Before Aging	650%, min	Before Aging	683%, min	
	After Aging	524%, min	After Aging	623%, min	
Freedom from Holes	Meets ASTM D5151-19 AQL=2.5		Meets ASTM D5151-19 AQL=2.5		Same
Protein Content	Meets ASTM D5712-2015		Meets ASTM D5712-2015		Same
Powdered residue	Meets ASTM D6124-06(Reapproved 2017)		Meets ASTM D6124-06(Reapproved 2017)		Same
Sterility	Non-sterile		Non-sterile		Same
Shelf life	3 Years		5 Years		Similar[1]
Single Use	Yes		Yes		Same
Label and labeling	Meet FDA's Requirement		Meet FDA's Requirement		Same

[1] The Shelf life of proposed device and predicate device is different; However, the product performance after 3 years has been determined based on accelerated aging study. The results can demonstrate that the performance of proposed device meets the ASTM D3578 requirements after 3 years accelerated aging.

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 D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
- ASTM D5712-15 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method
- ASTM D7160-05 Standard Practice for Determination of Expiration Dating for medical Gloves
- ISO 10993-1: 2009 Biological evaluation of medical devices - Part1: Evaluation and

testing within a risk management process

- 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 5: Tests For systemic toxicity

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D3578-19	Physical Dimension	The actual measured dimension of the gloves shall be meet the stated tolerance specified in Table 2 of the ASTM D3578-19 Width ± 10mm Length XS-S 220 min and M-XL 230 min Thickness (finger and Palm): 0.08 min	Meet the requirement
ASTM D3578-19	Determination of Physical Properties	Before and after accelerated aging, the gloves shall conform to the physical requirements in the Table 3 of ASTM D3578-19 Before Aging: Tensile Strength: 18 MPa min Stress Elongation: 5.5 MPa max Ultimate Elongation: 650% min After Accelerated Aging: Tensile Strength: 14 MPa min Ultimate Elongation: 500% min	Meet the requirement
ASTM D5151-19	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 AQL=2.5	Meet the requirement

ASTM D6124-06(2017)	Residual Powder Content Test	The powder residue content shall be not more than 2mg per glove.	Meet the requirement
ASTM D3578-19	Protein Content	≤ 200 ug/dm^2	Meet the requirement
ISO 10993-5:2009	In vitro Cytotoxicity	Non-cytotoxicity	Failed Potential toxicity Grade (3 or 4)
ISO 10993-10: 2010	Skin Sensitization	Non-sensitizing	Meet the requirement
ISO 10993-10: 2010	Skin irritation	Non-irritating	Meet the requirement
ISO 10993-11: 2017	Systemic toxicity	Non-systemic toxicity	Meet the requirement

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 Single-use medical latex examination gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K214017.