September 22, 2023

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

Re: K231446
Trade/Device Name: Single-Use Latex Sterile Surgical Gloves (SG100)
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: September 11, 2023
Received: September 11, 2023

Dear Kyra Kang:

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
DHT4B2: Personal Protective Equipment, Reprocessing & Disinfection Devices Team
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)*

K231446

Device Name

Single-Use Latex Sterile Surgical Gloves (SG100)

Indications for Use *(Describe)*

The Single-Use Latex Sterile Surgical Gloves are device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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

K231446

I. Submitter

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Preparation date: Sept. 19, 2023

Submission Correspondent

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US Agent

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II. Proposed Device

Device Trade Name:	Single-Use Latex Sterile Surgical Gloves
Model:	SG100
Common name:	Surgeon's Gloves
Regulation Number:	21 CFR 878.4460
Regulatory Class:	Class I
Product code:	KGO
Review Panel:	General Hospital

III. Predicate Device

510(k) Number:	K212848
Trade name:	Sterile Latex Surgical Gloves Powder Free
Common name:	Surgeon's Gloves Classification: Class I
Product Code:	KGO
Manufacturer	Pentavest Holdings Sdn Bhd

IV. Device Description

The proposed device, Single-Use Latex Sterile Surgical Gloves is a sterilized and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

The proposed device is made of natural rubber latex, per standard ASTM D3577- 09(15), the rubber surgical gloves classification is:

“ Type 1-gloves compounded primarily from nature rubber latex.” The gloves are powder-free and available in white in sizes 6, 6.5, 7, 7.5, 8, 8.5 and 9.

The proposed device is provided Radiation sterilized to achieve the sterility Assurance Level (SAL) of 10-6. The latex surgical glove shelf life is 3 years.

V. Indication for use

The Single-Use Latex Sterile Surgical Glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1 General Characteristic Comparison

Characteristic	Proposed device K231446	Predicate device K212848	Discussion
Product name	Single-Use Latex Sterile Surgical Gloves	Sterile Latex Surgical Gloves Powder Free	Similar
Indications For Use	The Single-Use Latex Sterile Surgical Glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	A Sterile Latex Surgical Gloves Powder Free is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	Similar
Product Code	KGO	KGO	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Powdered or Powder free	Powdered free	Powdered free	Same
Classification as per ASTM D3577- 2019	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	Same
Type of use	Over the counter use	Over the counter use	Same
Shelf Life	3 Years	3 Years	Same
Sterilization	Radiation, SAL- 10-6	Radiation, SAL- 10-6	Same
Single use	Yes	Yes	Same
Label and Labeling	Meet FDA's Requirement	Meet FDA's Requirement	Same
Protein Content	141µg/dm²	50µg/dm²	Similar

Table 2 Technological Characteristic Comparison

Characteristics	**Acceptance criteria of the standard**		**Remarks**
	Subject device K231446	**Predicate device K212848**	
Dimensions Length:- Min 265 mm	281 mm	380 mm	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Size			
6.0 (76+/-6mm)	76mm	74mm	Similar
6.5 (83+/-6mm)	84mm	86mm	Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
7.0 (89+/-6mm)	90mm	92mm	
7.5 (95+/-6mm)	96mm	98mm	
8.0 (102+/6mm)	102mm	105mm	
8.5 (108+/6mm)	109mm	110mm	
9.0 (114+/6mm)	115mm	116mm	
Cuff, Palm, Finger Tip Min 0.10 mm	Cuff- 0.16mm Palm-0.18mm Finger Tip- 0.22mm	Cuff- 0.12mm Palm-0.16mm Finger Tip- 0.21mm	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Tensile Strength 24Mpa minimum Before Aging	37Mpa	28.55Mpa	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Ultimate Elongation 750% minimum Before Aging	814%	870%	
Stress at 500% 5.5 MPa Max Before Aging	3.5Mpa	5.1Mpa	
Tensile Strength 18Mpa minimum After Aging	32.49Mpa	23.48Mpa	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Ultimate Elongation 560% minimum After Aging	760%	731%	

Characteristics	Acceptance criteria of the standard		Remarks
	Subject device K231446	**Predicate device K212848**	
Freedom from Holes AQL 1.5	AQL 1.5	AQL 1.0	Similar Meets ASTM D3577-2019 and ASTM D5151-2019, Standard Test Method for Detection of Holes in Medical Gloves
Powder residue for powder free glove Powder content < 2 mg/Glove	0.21 mg/Glove	0.40 mg/Glove	Similar Meets ASTM D3577-2019 and ASTM D6124-06,(Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

Characteristics	Acceptance criteria of the standard			Remarks
	Biocompatibility	**Subject device K231446**	**Predicate device K212848**	
Skin Irritation & Skin Sensitization	ISO 10993-10,Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Non- irritant and Non-Sensitizer	Non- irritant and Non-Sensitizer	Same
In vitro cytotoxicity	ISO 10993-5:2009(E),Biological Evaluation of Medical Devices - Part 5-Tests for in vitro Cytotoxicity	Cytotoxic	Cytotoxic	Same
Material Mediated pyrogenicity	ISO 10993-11:2017(E) ,Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity and USP 41 <151>Pyrogen Test	Non pyrogenic	No data available	-----
Acute Systemic Toxicity	ISO 10993-11:2017(E) ,Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity	Under the conditions of study the device extracts do not pose an acute systemic toxicity concern	Under the conditions of study the device extracts do not pose an acute systemic toxicity concern	Same
Bacterial Endotoxin	USP 42 <85>	<20EU/pair of gloves	<20EU/pair of gloves	Same

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 D3577-19: Standard Specification for Rubber Surgical Gloves.
- 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 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
- ISO 11137-1-2006/ (R) 2010 - validation of sterilization process
- ISO 11137-2:2013, sterilization of health care products - radiation - part 2: Establishing the sterilization dose

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D3577-19	Physical Dimension	The actual measured dimension of the gloves shall meet the stated tolerance specified in Table 2 of the ASTM D3577-19	Meets the requirement
ASTM D3577-19	Determination of Physical Properties	Before and after Accelerated aging, the gloves shall conform to the physical requirements in Table 3 of ASTM D3578-19	Meets 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	Meets the requirement AQL 1.5
ASTM D6124-06(2017)	Residual Powder Content Test	The powder residue content shall be not more than 2mg per gloves.	Meets the requirement
ASTM D5712-15	Protein Content	≤200μg/dm²	Meets the requirement
ISO 10993-10: 2010	Skin Sensitization	Non-sensitizing	Meets the requirement
ISO 10993-10: 2010	Skin irritation	Non-irritating	Meets the requirement
ISO 10993-11: 2017	Systemic toxicity	Non-systemic toxicity	Meets 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 this 510(K) submission, the Single-Use Latex Sterile Surgical Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212848.