May 22, 2026

Protect Gloves Company Limited
% Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K253060
Trade/Device Name: Sterile Latex Powder Free Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: April 22, 2026
Received: April 22, 2026

Dear Kiwi Xu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253060

Device Name
Sterile Latex Powder Free Surgical gloves

Indications for Use *(Describe)*
A Sterile Latex Powder Free Surgical Gloves is a 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.

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

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510(K) Summary

K253060

(As requirement by 21 CFR 807.92)

Date prepared: May 20, 2026

A. Applicant:

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B. Device:

Trade Name: Sterile Latex Powder Free Surgical Gloves

Model: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

Regulatory Information

Classification Name: Surgeon's Gloves
Classification: Class I
Product code: KGO
Regulation Number: 21 CFR 878.4460

Review Panel: General & Plastic Surgery

C. Predicate device:

K212848
Applicant: Pentavest Holdings Sdn Bhd
Device Name: Sterile Latex Surgical Gloves powder free

Regulatory Information

Classification Name: Surgeon's Gloves

Classification: Class I

Product code: KGO

Regulation Number: 21 CFR 878.4460

Review Panel: General & Plastic Surgery

D. Indications for use of the device:

A Sterile Latex Powder Free Surgical Gloves is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

E. Device Description

Sterile Latex Powder Free Surgical Gloves are sterile, disposable, and powder-free. The gloves are made of natural rubber. The glove is designed to meet the specification of ASTM D3577-19 Standard Specification for Rubber Surgical Gloves. The glove has a shelf life of 3 years, is white in color and comes in the following sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0.

F. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	K253060	K212848	-
Manufacturer	Protect Gloves Company Limited	Pentavest Holdings Sdn Bhd	-
Product Name	Sterile Latex Powder Free Surgical Gloves	Sterile Latex Surgical Gloves Powder Free	Similar
Product Code	KGO	KGO	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Indications for use	A Sterile Latex Powder Free Surgical Gloves 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.	Same
Powder/Powder free	Powder free	Powder free	Same
Material	Natural rubber	Natural rubber	Same
Classification as per ASTM D3577-19, Standard Specification for Rubber Surgical Gloves	Type I-gloves compounded primary from natural rubber latex	Type I-gloves compounded primary from natural rubber latex	Same
Size	5.5 6.0 6.5	6.0 6.5 7.0 7.5	Similar

Device	Proposed Device	Predicate Device	Result
	7.0 7.5 8.0 8.5 9.0	8.0 8.5 9.0	
Sterilization	Radiation SAL-10^{-6}	Radiation SAL-10^{-6}	Same
Use	Singe use	Single use	Same
Label and Labeling	Meet FDA's label requirements	Meet FDA's label requirements	Same
Type of use	OTC	OTC	Same
Shelf-life	Three years	Three years	Same

Table 2 Technical Comparison of Proposed and Predicate Devices

Characteristic	**Subject device**	**Predicate device** K212848	**Comparison**
Dimensions Length: 5.5(Min 245mm) 6.0-9.0 (Min 265mm)	5.5: 288-292 mm 6.0: 276-280 mm 6.5: 278-280 mm 7.0: 280-286 mm 7.5: 279-285 mm 8.0: 280-285 mm 8.5: 280-282 mm 9.0: 289-290 mm	380mm	Different
Width 5.5(70±6mm) 6.0(76±6mm) 6.5 (83±6mm) 7.0 (89±6mm) 7.5 (95±6mm) 8.0 (102±6mm) 8.5 (108±6mm) 9.0 (114±6mm)	5.5: 73-75mm 6.0: 79-80 mm 6.5: 84-85mm 7.0: 89-91 mm 7.5: 95-97 mm 8.0: 100-101 mm 8.5: 109-110 mm 9.0: 114-115 mm	74 mm 86 mm 92 mm 98 mm 105 mm 110 mm 116 mm	Similar
Cuff, Palm, Finger Tip Min 0.10mm	Cuff: 0.13-0.18mm Palm:0.15-0.19mm Finger: 0.17-0.20mm	Cuff: 0.12 mm Palm:0.16 mm Finger: 0.21 mm	Similar
Tensile Strength 24Mpa minimum (Before aging)	26.22-33.06MPa	28.55 MPa	Similar
Ultimate Elongation 750% minimum (Before aging)	809.45-888.74%	870 %	Similar

Characteristic	Subject device	Predicate device K212848	Comparison
Stress at 500% 5.5 Mpa Max (Before aging)	4.14-5.04MPa	5.1MPa	Similar
Tensile Strength 18Mpa minimum (after aging)	23.23-28.36 MPa	23.48 MPa	Similar
Ultimate Elongation 560% minimum (after aging)	809.97-888.06%	731%	Similar
Freedom from holes AQL 1.5	AQL 1.5	AQL 1.0	Different 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 <2mg/glove	0.68-0.70 mg/glove	0.40 mg/glove	Different
Aqueous Extractable Protein Content ≤200ug/dm^2	163.65-184.24 ug/dm^2	50 ug/dm^2	Different
Skin Irritation & Skin Sensitization	Non-irritant and non-sensitizing	Non-irritant and non sensitizer	Same
In-vitro cytotoxicity	Cytotoxic	Cytotoxic	Same
Acute 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	<20EU/pair of gloves	<20EU/pair of gloves	Same

Analysis:

The length and powder residue of the gloves are slightly different from those of the predicate device. But the proposed gloves have been tested according to ASTM D3577-19 (2023) for dimensions and ASTM D6124-06 (2022) for powder residue respectively, and both dimensions and powder residue met the requirements of ASTM D 3577-19. The protein content of the proposed device is larger than that of the predicate device. However, the proposed device doesn't have special label claim of 50 ug/dm^2 or less per glove of extractable protein and has been conducted the testing of aqueous extractable protein content according to ASTM D3577 and met its requirement.

In addition, the proposed device use different AQL of water tightness test to the predicate device, but the AQL 1.5 is complied with the ASTM D 3577-19 and ASTM D5151-19, and can demonstrate the effectiveness of the proposed device.

Thus, such differences won't raise any concerns of safety and effectiveness of the proposed device.

G. Summary of Non-Clinical Testing

- **Biocompatibility**

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the subject device is external communicating device: tissue/bone/dentin and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to evaluated the biocompatibility of Sterile Latex Powder free Surgical gloves:

- ISO 10993-05:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In VitroCytotoxicity
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation
- ISO 10993-11:2017 Biological evaluation of medical device – Part 11: Tests for systemic toxicity

- **Performance Testing**

Physical performance testing of the proposed device were conducted as per ASTM D3577-19 Standard Specification for Rubber Surgical Gloves. Extractable Protein Test was conducted to for the determination of protein levels in the gloves according to ASTM D3577 Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method.
To summarize, the performance testing of the subject device were conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- 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 2022) Standard Test Method for Residual Powder on Medical Gloves
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D3078-02 (2013) Standard Test Method for Determination of Leakage in Flexible Packaging by Bubble Emission Method
- ASTMF88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D7160-16 Determination of Expiration Date for Medical Gloves

Performance testing and biocompatibility testing are summarized in below table 3.

Table 3: Summary of Performance Testing & Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Dimension ASTM D3577-19	To determine the length of the gloves	Length: 5.5(Min 245mm) 6.0-9.0 (Min 265mm)	Pass 5.5: 288-292 mm 6.0: 276-280 mm 6.5: 278-280 mm 7.0: 280-286 mm 7.5: 279-285 mm

Test Methodology	Purpose	Acceptance Criteria	Result
			8.0: 280-285 mm 8.5: 280-282 mm 9.0: 289-290 mm
	To determine the width of the gloves	5.5(70±6mm) 6.0(76±6mm) 6.5 (83±6mm) 7.0 (89±6mm) 7.5 (95±6mm) 8.0 (102±6mm) 8.5 (108±6mm) 9.0 (114±6mm)	Pass 5.5: 73-75mm 6.0: 79-80 mm 6.5: 84-85mm 7.0: 89-91 mm 7.5: 95-97 mm 8.0: 100-101 mm 8.5: 109-110 mm 9.0: 114-115 mm
	To determine the thickness of the gloves	Palm:0.10min Finger: 0.10 min Cuff: 0.10 min	Pass Cuff: 0.13-0.18mm Palm:0.15-0.19mm Finger: 0.17-0.20mm
Physical Properties ASTM D3577-19	To determine the physical property of tensile strength of the gloves	**Before Aging** Tensile strength 24Mpa min for all sizes **After Aging** Tensile strength 18Mpa min for all sizes	Pass **Before Aging** 26.22-33.06MPa for all sizes **After Aging** 23.23-28.36 MPa for all sizes
	To determine the physical property of ultimate elongation of the gloves	**Before Aging** 750% min for all sizes **After Aging** 560% min for all sizes	Pass **Before Aging** 809.45-888.74% for all sizes **After Aging** 809.97-888.06% for all sizes
	To determine the physical properties of stress at 500% elongation of the gloves	**Before Aging** 5.5Mpa, max for all sizes	Pass **Before Aging** 3.07-3.98MPa
Watertight Test ASTM D5151-19	To determine the watertightness of the gloves	AQL 1.5	Pass No glove appears leakage for the size of 750 gloves have been tested.
Residual power ASTM D6124-06	To determine the residual power in the gloves.	2mg per glove or less	Pass 0.68-0.70 mg/glove for all tested gloves
Aqueous soluble protein content ASTM D5712-15	To determine the aqueous soluble protein content in the gloves	200 μ g/dm^2 max for all sizes.	Pass 163.65-184.24 ug/dm^2 for all tested gloves.

Test Methodology	Purpose	Acceptance Criteria	Result
Irritation ISO 10993-23:2021	To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits.	Negligibly irritating	Pass Under the condition of this study, the device is negligibly irritating.
Sensitization ISO 10993-10:2021	The test was designed to evaluate the potential of a test article to cause skin sensitization.	Non-sensitizing	Pass Under the conditions of the study, the device is non-sensitizing
Acute Systemic toxicity ISO 10993-11	The test article was evaluated to determine whether leachables extracted from the test article would cause acute systemic toxicity following injection into mice.	Non-acute systemic toxicity	Pass Under the conditions of the study, there is no mortality or evidence of acute systemic toxicity from the extracts.
Material Mediated Pyrogenicity USP <151>	To determine whether the device elicits a febrile reaction.	Not pyrogenic	Pass Under the conditions of the study, not pyrogenic.
Bacterial Endotoxin USP 43 <161>	To determine the bacterial endotoxin of each sample meet the requirement of endotoxin limit.	<20EU/pair of gloves	Pass Under the conditions of the test, the bacterial endotoxin of each test article was less than 20 EU/pair.
Shelf life ASTM D7160-16 (2023)	To validate the shelf life of the proposed device.	Three years	Pass

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Sterile Latex Powder Free Surgical Glove is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K212848.