March 23, 2023

Suzhou Colour-way New Material Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14 th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K222620
Trade/Device Name: Sterilized Latex Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: February 24, 2023
Received: February 24, 2023

Dear Ivy Wang:

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
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)*
K222620

Device Name
Sterilized Latex Surgical Gloves

Indications for Use *(Describe)*
The Sterilized Latex Surgical Glove 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.

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510(K) Summary

K222620

(As requirement by 21 CFR 807.92)

Date prepared: March 23, 2023

A. Applicant:

Name: Suzhou Colour-way New Material Co., Ltd.
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Submission Correspondent:
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Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device:

Trade Name: Sterilized Latex Surgical Gloves
Model: 6.5, 7, 7.5, 8, 8.5, 9

Regulatory Information
Classification Name: Surgeon's Gloves
Classification: Class I
Product code: KGO
Regulation Number: 21 CFR 878.4460
Review Panel: General Hospital

C. Predicate device:

K212596
Applicant: Amazing Rubber Products Pvt. Ltd.
Device Name: Sterile Latex Surgical Gloves Power Free

Regulatory Information
Classification Name: Surgeon's Gloves
Classification: Class I
Product code: KGO
Regulation Number: 21 CFR 878.4460
Review Panel: General Hospital

D. Indications for use of the device:

The Sterilized Latex Surgical Glove 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

The proposed sterilized latex surgical gloves are powder-free, sterile, single use, surgical gloves intended to be worn by operating room personnel to protect a surgical wound from contamination. The gloves are natural color (no colorant added). The gloves are offered in sizes of 6.5, 7, 7.5, 8, 8.5, 9.
The gloves are designed and manufactured in accordance with the ASTM D3577-19 standard.

F. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	K222620	K212596	-
Manufacturer	Suzhou Colour-way New Material Co., Ltd.	Amazing Rubber Products Pvt. Ltd.	-
Product Name	Sterilized Latex Surgical Gloves	Sterile Latex Surgical Gloves Power Free	Similar
Product Code	KGO	KGO	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Indications for use	The Sterilized Latex 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.	Same
Powder/Powder free	Powder free	Powder free	Same
Material	Natural rubber	Natural rubber	Same
Classification as per ASTM D3577-09, Standard Specification for Rubber Surgical Gloves	Type I-gloves coumpounded primary from natural rubber latex	Type I-gloves coumpounded primary from natural rubber latex	
Size	6.5 7.0 7.5	6.0 6.5 7.0	Similar

	8.0 8.5 9.0	7.5 8.0 8.5 9.0	
Sterilization	Radiation SAL-10^{-6}	ETO/as well as Radiation, SAL-10^{-6}	Similar
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 K212596**	**Comparison**
Dimensions Length: Min 265mm	6.5: 272-278mm 7.0: 274-279mm 7.5: 276-283mm 8.0: 278-284mm 8.5: 279-287mm 9.0: 282-288mm	486mm	Different
Width 6.5 (83±6mm) 7.0 (89±6mm) 7.5 (95±6mm) 8.0 (102±6mm) 8.5 (108±6mm) 9.0 (114±6mm)	 6.5: 84-85mm 7.0: 90-92mm 7.5: 95-97mm 8.0: 103-105mm 8.5: 108-110mm 9.0: 114-116mm	 6.5 (87mm) 7.0 (91mm) 7.5 (97mm) 8.0 (103mm) 8.5 (110mm) 9.0 (116mm)	Similar
Cuff, Palm, Finger Tip Min 0.10mm	Cuff: 0.14-0.16mm Palm:0.18-0.21mm Finger: 0.22-0.25mm	Cuff: 0.16mm Palm:0.21mm Finger Tip: 0.33mm	Similar
Tensile Strength 24Mpa minimum (Before aging)	26.9-29.3MPa	28.61Mpa	Similar
Ultimate Elongation 750% minimum (Before aging)	800-950%	871%	Similar
Stress at 500% 5.5 Mpa Max (Before aging)	3.3-4.9MPa	5.1Mpa	Similar
Tensile Strength 18Mpa minimum (after aging)	21-26.3MPa	24.12Mpa	Similar

Ultimate Elongation 560% minimum (after aging)	650-790%	732%	Similar
Freedom from holes AQL 1.5	AQL 1.5	AQL 1.0	Different
Powder residue for powder free glove powder content <2mg/glove	1.2-1.5mg/glove	0.38mg/glove	Different
Aqueous Extractable Protein Content ≤200ug/dm^2	93.6-125.1 ug/dm^2	46.40 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
Material Mediated pyrogenicity	Non pyrogenic	Non pyrogenic	Same
Systemic toxicity	Under the conditions of study, the device extracts do not pose a systemic toxicity concern.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern.	Same
Bacterial Endotoxin	<20EU/pair of gloves	<20EU/pair of gloves	Same

Analysis:

The subject sterilized latex surgical gloves are substantially equivalent to the predicate device, in terms of indications for use, material composition, sizes, shelf-life and performance. 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 D3767 (03)-2014 for dimensions and ASTM D6124-06 (2017) 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 contenct according to ASTM D5712 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

Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to evaluated the biocompatibility of Sterilized Latex Surgical Gloves:

• ISO 10993-05:2009 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
• 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 D5712-2015 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 2017) Standard Test Method for Residual Powder on Medical Gloves
• ASTM D5712-2015 Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method
• 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 D3577-09**	To determine the length of the gloves	265mm, min	Pass 6.5: 272-278mm 7.0: 274-279mm 7.5: 276-283mm 8.0: 278-284mm 8.5: 279-287mm 9.0: 282-288mm
	To determine the width of the gloves	Size 6.5: 83 ± 6 mm Size 7: 89 ± 6 mm Size 7.5: 95 ± 6 mm	Pass 6.5: 84-85mm 7.0: 90-92mm 7.5: 95-97mm

		Size 8: 102 ± 6 mm Size 8.5: 108 ± 6 mm Size 9: 114 ± 6 mm	8.0: 103-105mm 8.5: 108-110mm 9.0: 114-116mm
	To determine the thickness of the gloves	Palm:0.10, min Finger: 0.10 min Cuff: 0.10 min	Pass Cuff: 0.14-0.16mm Palm:0.18-0.21mm Finger: 0.22-0.25mm
Physical Properties ASTM D3577-09	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** 26.9-29.3MPa or all sizes **After Aging** 21-26.3MPa 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	**Before Aging** 800%-950% for all sizes **After Aging** 650%-790%for all sizes
	To determine the physical properties of stress at 500% elongation of the gloves	**Before Aging** 5.5Mpa, max for all sizes	**Before Aging** 3.3-4.9MPa
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 (17)	To determine the residual power in the gloves.	2mg per glove or less	Pass 1.2-1.5mg/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 93.6-125.1 ug/dm^2 for all tested gloves.
Irritation ISO 10993-10	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	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
Systemic toxicity ISO 10993-11	The test article was evaluated to determine whether leachables	Non-systemic toxicity	Pass Under the conditions of the study, there is no mortality or

	extracted from the test article would cause acute systemic toxicity following injection into mice.		evidence of systemic toxicity from the extracts.
Pyrogen **ISO 10993-11**	The test article was evaluated for the risks of febrile reaction in the rabbit to the administration by injection.	Non-pyrogenic	Pass Under the conditions of the study, the test articles would not considered be febrile reaction.
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**	To validate the shelf life of the proposed device.	Three years	Pass Accelerated aging validation were carried out to the sterilized latex surgical gloves. In addition, 13 samples for each lot have already been picked for real-time stability testing at 6th and 9th month of storage. Performance and package before and after aging were acceptable and met the requirements.

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 Sterilized Latex Surgical Gloves is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K212596.