August 9, 2023

Puyang Linshi Medical Supplies Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K230304
Trade/Device Name: Polyisoprene Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: July 8, 2023
Received: July 11, 2023

Dear Boyle 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,

Allan Guan -S

For 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.

510(k) Number *(if known)*
K230304

Device Name
Polyisoprene Surgical Gloves

Indications for Use *(Describe)*
The Polyisoprene Surgical Gloves are sterile and single use device intended to be worn on the hands of 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 (K230304)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR 807.92.

1.0 submitter's information

Name: Puyang Linshi Medical Supplies Co., Ltd.
Address: East of Panjin Road and North of Fumin Road in Puyang County, Puyang City, Henan Province 457001, China.
Phone Number: +86-19839327898
Contact: Catherine Liu
Date of Preparation: 08.01.2023

Designated Submission Correspondent
Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
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2.0 Device information

Trade name: Polyisoprene Surgical Gloves
Common name: Surgeon's Gloves
Classification name: Surgeon's Gloves
Model(s): 6.5, 7, 7.5, 8

3.0 Classification

Production code: KGO
Regulation number: 21CFR878.4460
Classification: Class I
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Better Care Plastic Technology Co., Ltd.
Device: Sterile Polyisoprene Powder Free Surgical Gloves
510(k) number: K171047

5.0 Indications for use

The Polyisoprene Surgical Gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

6.0 Device description

The proposed device is Polyisoprene Surgical Gloves, sterile and disposable devices. The proposed devices are made of polyisoprene. The proposed device is white. The design of proposed device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D3577.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

Item	Proposed device	Predicated device	Remark
510(k) number	K230304	K171047	
Product Code	KGO	KGO	Same
Regulation No.	21CFR878.4460	21CFR878.4460	Same
Class	I	I	Same
Indications for Use	The Polyisoprene Surgical Gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.	This surgeon's glove is a sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.	Same
Prescription or Over The Counter Use	Over-The-Counter-Use	Over-The-Counter-Use	Same
Materials	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Same
Design	Single use	Single use	Same
	Sterile	Sterile	Same
	Powder-free	Powder-free	Same
	Hand Specific	Hand Specific	Same
	Beaded cuff	Beaded cuff	Same
Color	White	Clear	Difference 1
Dimensions and physical properties	Meets ASTM D3577- 2019	Meets ASTM D3577-09 (2015)	Difference 2
Sterilization method	EO Sterilization	Radiation	Difference 3
Sterility Assurance	10^{-6} SAL	10^{-6} SAL	Same

Level (SAL)			
Freedom from holes	Meets ASTM D3577- 2019 Clause 8.3 (ASTM D5151-19) Inspection level/AQL: GI/AQL 1.5	Meets ASTM D3577- 09(2015) Inspection level/AQL: GI/AQL 1.5	Difference 2
Powder-Free	Meets ASTM D 6124-06 The averaged residual powder content for the glove during process validation is 0.1mg per glove	Meets ASTM D 6124-06 The averaged residual powder content for the glove during process validation is 0.16mg per glove	Similar
Primary Skin Irritation ISO 10993- 10:2010	Under the conditions of the study (per ISO 10993-23), the device is not an irritant	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Difference 4
Dermal Sensitization - ISO 10993-10:2010	Under the conditions of the study (per ISO 10993-10), not a sensitizer	Under the conditions of the study (per ISO 10993-10), not a sensitizer	Same
Acute Systemic Toxicity - ISO 10993-11: 2006	Under the conditions of the study, there was no mortality or evidence of Acute systemic toxicity	Under the conditions of the study, there was no mortality or evidence of Acute systemic toxicity	Same
Shelf Life	2 years	3 years	Difference 5

Analysis：

Difference 1: The colors of proposed device are different with those of the predicate, but they all meet the requirements of ASTM D3577-19, so the differences do not raise any new safety or performance questions.

Difference 2: The proposed device and the predicate device meet different requirements ASTM D3577-19 and ASTM D3577-09 as the ASTM D3577-19 is the only Consensus Standard for Rubber Surgical Gloves Recognized by FDA, but the differences do not raise any new safety or performance questions.

Difference 3: The proposed device and the predicate device sterilized by different methods EO Sterilization and Radiation, but the EO validation of proposed device was implemented based on ISO 11135:2014, including sterilizer installation, OQ, PPQ and MPQ of sterilization. And parameters in Sterilization Validation Report can prove these products being SAL of 10-6.

Difference 4: New standard ISO10993-23:2021 replaces the Skin Irritation test in ISO10993-10:2010.

Difference 5: The shelf life of proposed device is verified by Product Performance Test Report after 2 Years Accelerated Aging.

8.0 Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 2 Summary of Non-Clinical Performance Testing

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
1	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	All grades are 0. All animals were survived, and no abnormal signs were observed during the study.
2	ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation		Skin Irritation Test: If the primary irritation index is 0-0,4, the response category is Negligible. 0,5-1,9 means slight 2-4,9 means moderate 5-8 means severe	The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition
3	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	The viab.% of the 100% extract of the test article is the final result, and if viability is reduced to <70% of the blank, it has cytotoxic potential.	Viab.% of 100% test article extract is 6.1% It means the proposed device have potential toxicity to L-929 in the MTT method
4	ISO 10993-11: 2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	To evaluate the potential for medical device materials to cause adverse systemic reactions.	Within the monitoring period (72 h), if the toxicosis response of testing group is not greater than that of control group, the testing sample is regarded as acceptable.	There was no evidence of systemic toxicity from the extract.

5	ISO 10993-7 standards for EO/ECH residual testing	This part of ISO 10993 specifies allowable limits for residual ethylene oxide (EO)	Limit (< 24 h) EO 4 mg ECH 9 mg Prolonged (> 24 h < 30 d) EO 60 mg/30 d ECH 60 mg/30 d	EO residue: ≤ 4mg in the first 24h; ≤ 60mg in the first 30d; EO residue shall also ≤ 10ug/g; ECH residue: ≤ 9mg in the first 24h; ≤ 60mg in the first 30d.

6	ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves	powder residue limit of 2.0 mg	0.1mg /glove
7	ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves. 12/23/2019	This test method covers the detection of holes in medical gloves.	Samples number: 200 gloves AQL: 1.5 (ISO 2859) Criterion ≤7 gloves for water leakage	0 glove water leakage found
8	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	This test method, for the determination of protein levels in latex, is primarily intended to test NR, latex, and elastomeric materials for residual protein content.	Have a recommended aqueous soluble protein content limit of 200 ug/dm^2	52ug/dm^2

9	ASTM D3577-19, Standard Specification for Rubber Surgical Gloves	The specification is intended as a reference to the performance and safety of rubber surgical gloves. The safe and proper use of rubber surgical gloves is beyond the scope of this specification.	Dimensions: -6.5: width 83±6mm Length ⩾265 mm -7: width 89±6mm Length ⩾265 mm -7.5: width 95±6mm Length ⩾265 mm -8: width 102±6mm Length ⩾265 mm Thickness: -Finger ⩾0.10 mm -Palm ⩾0.10 mm -Cuff ⩾0.10 mm Physical properties: ● Before aging ● Tensile strength ⩾17MPa ● Ultimate ● Elongation ≥ ● 650% ● Stress at 500% Elongation ≤ 7.0 MPa ● ● After Accelerated Aging ● Tensile strength ● ≥12MPa ● Ultimate Elongation ≥ 490%	Dimensions: 6.5: width: 83-84 mm Length 280-289 mm Thickness: Finger 0.230-0.260 mm Palm 0.188-0.207 mm Cuff 0.137-0.151 mm 7: width 91-93 mm Length 271-278 mm Thickness: Finger 0.211-0.241 mm Palm 0.181-0.193 mm Cuff 0.133-0.144 mm 7.5: width 96-98 mm Length 273-280 mm Thickness: Finger 0.218-0.237mm Palm 0.180-0.192 mm Cuff 0.136-0.146 mm 8: width 103-105 mm Length 268-283 mm Thickness: Finger 0.221-0.272 mm Palm 0.189-0.212 mm Cuff 0.143-0.153 mm Physical properties: Before aging -Tensile strength 25.2-30.9 MPa -Ultimate Elongation 721% - 777% -Stress at 500% Elongation 6.5-7.0 MPa After Accelerated Aging -Tensile strength 23.0-29.0 MPa -Ultimate Elongation 680% - 716%

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.