U.S. FOOD & DRUG ADMINISTRATION

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February 1, 2021

Guilin HBM Health Protections, Inc.
℅ Shelley Li
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 703, 705, Baohua International Plaza,
West Guangzhong Road 555, Jingan
Shanghai, 200071
China

Re: K203483
Trade/Device Name: Medispo Rubber Surgical Gloves, Medispo 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: November 19, 2020
Received: November 27, 2020

Dear Shelley Li:

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,

For: Elizabeth F. Claverie-Williams, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203483

Device Name
1) Medispo Rubber Surgical Gloves
2) Medispo Polyisoprene Surgical Gloves

Indications for Use *(Describe)*
The Medispo Rubber/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.

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510(k) Summary: K203483

I. Submitter

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin, China

Contact person: Pu Lei
Position: QC Manager
Tel.: +86-13707738532
E-mail: pulei@hbmchina.com

Preparation date: Jan. 11, 2021

II. Proposed Device

Device Trade Name	1) Medispo Rubber Surgical Gloves 2) Medispo Polyisoprene Surgical Gloves
Common name:	Surgeon's gloves
Regulation Number:	21 CFR 878.4460
Regulatory Class:	Class I
Product code:	KGO
Review Panel	General Hospital

III. Predicate Devices

a.

510(k) Number:	K171047
Trade name:	Sterile Polyisoprene Powder Free Surgical Gloves
Common name:	Surgeon’s Gloves
Classification:	Class I
Product Code:	KGO
Manufacturer	Better Care Plastic Technology Co., Ltd.

b.

510(k) Number:	K192328
Trade name:	JR Medic Latex Surgeon’s Gloves Sterile Powder Free
Common name:	Surgeon’s Gloves
Classification:	Class I
Product Code:	KGO
Manufacturer	JR Engineering & Medical Technologies (M) SDN.BHD.

IV. Device description

The proposed devices, surgical gloves, are sterile and disposable devices.
There are two types of surgical gloves according to the raw materials in this submission:

- Type 1-Natural rubber surgical gloves
- Type 2-Synthetic polyisoprene surgical gloves

The proposed devices are powder-free gloves with creamy white in color. There are seven sizes (6", 6.5", 7", 7.5", 8", 8.5", 9") available for the gloves whichever are smooth- or texture-surfaced, with or without a rolled rim at the cuff edge.
The gloves are sterilized by ionizing irradiation. The shelf-life is three (3) years.

V. Indication for use

The 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.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Natural Rubber Surgical Gloves

Item	Proposed device (K203483)	Predicate device (K192328)	Discussion
Product name	Medispo Rubber Surgical Gloves	JR Medic Latex Surgeon's Gloves Sterile Powder Free	-
Product Code	KGO	KGO	Same
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	Same
Classification	Class I	Class I	Same
Gloves classification	Type I, Surgeon's gloves	Type I, Surgeon's gloves	Same
Powder free	Yes	Yes	Same
Indication for use	The 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.	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	Same
Main Material	Natural rubber	Natural rubber	Same
Color	Creamy white	Creamy white	Same
Palm width	6.0 (76mm±5mm) 6.5 (83mm±5mm) 7.0 (89mm±5mm)	6.0 (78mm) 6.5 (85mm) 7.0 (88mm)	Similar

	7.5 (95mm±5mm) 8.0 (102mm±6mm) 8.5 (108 mm±6mm) 9 (114mm±6mm)	7.5 (97mm) 8.0 (103mm) 8.5 (110mm) 9(116mm)	
Length	6.0 (265mm min) 6.5 (265mm min) 7.0 (270mm min) 7.5 (270mm min) 8.0 (270mm min) 8.5 (280mm min) 9 (280mm min)	300 mm	Different
Thickness	Cuff: min 0.10mm Palm: min 0.13mm Finger tip: min 0.13mm	Cuff: 0.11mm Palm: 0.18mm Finger tip: 0.21mm	Similar
Freedom from holes	Meets requirements of the ASTM D3577-19	Meets requirements of the ASTM D3577-09(2015)	Similar
Physical Properties (before aging)	Meets requirements of the ASTM D3577-19	Meets requirements of the ASTM D3577-09(2015)	Similar
Physical Properties (after aging)	Meets requirements of the ASTM D3577-19	Meets requirements of the ASTM D3577-09(2015)	Similar
Powder residual	≤2.0 mg/glove	≤2.0 mg/glove	Same
Special label claim	No protein labeling statement	Protein content label claim of 50μg/dm² or less	Different
Sterility	Sterile	Sterile	Same
Sterilization method	Radiation	Radiation	Same
For single use	Yes	Yes	Same
Type of use	Over the counter use	Over the counter use	Same
Biocompatibility	Conform to the requirements of ISO 10993 series standards	Conform to the requirements of ISO 10993 series standards	Same

Table 2 Comparison of Polyisoprene Surgical Gloves

Item	Proposed device (K203483)	Predicate device (K171047)	Discussion
Product name	Medispo Polyisoprene Surgical Gloves	Sterile Polyisoprene Powder Free Surgical Gloves	-
Product Code	KGO	KGO	Same
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	Same
Classification	Class I	Class I	Same
Gloves classification	Type II, Surgeon's gloves	Type II, Surgeon's gloves	Same
Powder free	Yes	Yes	Same
Indication for use	The 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.	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	Same
Main Material	Synthetic Polyisoprene	Synthetic Polyisoprene	Same
Color	Creamy white	Creamy white	Same
Palm width	6.0 (76mm±5mm) 6.5 (83mm±5mm) 7.0 (89mm±5mm) 7.5 (95mm±5mm) 8.0 (102mm±6mm) 8.5 (108 mm±6mm 9 (114mm±6mm)	5.5 (70mm) 6.0 (76mm) 6.5 (83mm) 7.0 (89mm) 7.5 (95mm) 8.0 (102mm) 8.5 (108mm) 9 (114mm)	Similar
Length	6.0 (265mm min) 6.5 (265mm min) 7.0 (270mm min) 7.5 (270mm min) 8.0 (270mm min) 8.5 (280mm min) 9 (280mm min)	Minimum 265 Average 305 mm	Similar
Thickness	Cuff: 0.10mm min Palm: 0.13mm min Finger tip: 0.13mm min	Cuff: 0.10mm min Palm: 0.10mm min Finger tip : 0.10mm min	Similar
Freedom from	Meets requirements of the	Meets requirements of the	Similar

holes	ASTM D3577-19	ASTM D3577-09(2015)	
Physical Properties (before aging)	Meets requirements of the ASTM D3577-19	Meets requirements of the ASTM D3577-09(2015)	Similar
Physical Properties (after aging)	Meets requirements of the ASTM D3577-19	Meets requirements of the ASTM D3577-09(2015)	Similar
Powder residual	≤2.0 mg/glove	≤2.0 mg/glove	Same
Sterility	Sterile	Sterile	Same
Sterilization method	Radiation	Radiation	Same
For single use	Yes	Yes	Same
Type of use	Over the counter use	Over the counter use	Same
Biocompatibility	Conform to the requirements of ISO 10993 series standards	Conform to the requirements of ISO 10993 series standards	Same

The performance test of the subject devices were performed on the final finished device. The test results show the subject devices meet the requirements of ASTM D3577-19.

VII. Summary of Non-Clinical Testing

Non-clinical performance tests were conducted in accordance with relevant standards to verify that the proposed device met all design specifications.

Items	Methodology / Standard	Acceptance Criteria	Results
Palm width	ASTM D3767-03(2020)	6.0 (76mm±5mm) 6.5 (83mm±5mm) 7.0 (89mm±5mm) 7.5 (95mm±5mm) 8.0 (102mm±6mm) 8.5 (108 mm±6mm) 9 (114mm±6mm)	Pass

Length	ASTM D3767-03(2020)	6.0 (265mm min) 6.5 (265mm min) 7.0 (270mm min) 7.5 (270mm min) 8.0 (270mm min) 8.5 (280mm min) 9 (280mm min)	Pass
Thickness	ASTM D3767-03(2020)	Cuff: min 0.10mm Palm: min 0.13mm Finger tip: min 0.13mm	Pass
Freedom from holes	ASTM D5151-19	Freedom free hole AQL 1.5	Pass
Physical Properties (before aging)			
Tensile Strength	ASTM D412-16	≥24 MPa	Pass
Ultimate Elongation	ASTM D412-16	≥750%	Pass
Physical Properties (after aging)			
Tensile Strength	ASTM D412-16	≥18 MPa	Pass
Ultimate Elongation	ASTM D412-16	≥560%	Pass
Powder residual	ASTM D6124-06(2017)	2mg per glove	Pass

The relevant standards used in the submission are listed as below:

- ASTM D3577-19, Standard Specification for Rubber Surgical Gloves
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5712-15, Standard Test Method for The Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
- ASTM D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

- USP 42/NF37 <151> Pyrogen Test
- USP 36_NF 31<71>Sterility Test
- ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
- ISO 10993-5: 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, Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
- ISO 10993-4:2017, Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
- ASTM F756-17 Standard Practice for assessments of hemolytic properties of material

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

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