October 26, 2022

Hebei Titans Hongsen Medical Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K221374
Trade/Device Name: Disposable Medical Rubber Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: September 27, 2022
Received: September 27, 2022

Dear Ray 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, 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)*
K221374

Device Name
Disposable Medical Rubber Examination Gloves

Indications for Use *(Describe)*
Disposable Medical Rubber Examination Gloves are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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 K221374

1. Date of Preparation: 10/25/2022

2. Submitter

Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone, Nangong City, Xingtai City, 051800, Hebei, China

Contact Person: Chai Wu
Position: Quality Director
Tel: +86-17769045117
Email: hszj@titans-cn.com

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Subject Device Identification

Trade Name: Disposable Medical Rubber Examination Gloves

Common Name: Latex Patient Examination Glove

Regulatory Information:
Classification: I
Product Code: LYY
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

5. Predicate Device Identification

K210253

BEST GLOVE -LATEX POWDER FREE EXAMINATION GLOVE

BESTSAFE GLOVE CO., LTD

Regulatory Information:

Classification: I

Product Code: LYY

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Common Name: Latex Patient Examination Glove

6. Device Description

The Disposable Medical Rubber Examination Gloves are manufactured to meet the all current specifications listed under the ASTM Specification D3578-19, Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex.
These gloves are natural in color (no color is added) and are powder free.

The proposed device(s) are sold non-sterile and are intended to be single-use, disposable devices.

Characteristics	Subject Device		
Single use	Single use		
Sterile/Non Sterile	Non Sterile		
Dimension	Length (mm): 230 min.		
	Width (mm)		
	Size		Width
	XS		75±5
	S		85±5
	M		95±5
	L		105±5
	XL		115±5
	Thickness (mm) For all sizes: 0.08 min.		
Physical Properties	Type I		
		Before Aging	After Accelerated Aging
	Tensile Strength	18MPa, min	14 MPa, min
	Ultimate Elongation	650 % min	500 % min
Freedom from holes	No water leakage is inspected. AQL 2.5		
Powder Free Residue	Size	Residual powder content (mg/glove)	
	XS	0.28	
	S	0.25	
	M	0.31	
	L	0.25	
	XL	0.35	

Protein Content	Meet the requirements of ASTM D5712, Less than 200 μg/dm^2
Biocompatibility	Biocompatible

7. Indication For Use Statement

Disposable Medical Rubber Examination Gloves are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

8. Technological Characteristic Comparison Summary

The subject device has same indication for use, design (single use, non-sterile), powdered free and material with the predicate device.

The subject is different with the predicate device in dimensions, physical properties, powder free residue and protein content. But both subject device and predicate device meet the requirements of ASTM D3578-19, Standard Specification for Rubber Examination Gloves, so we conducted the testing as this standard, the test results show that the subject device meet the requirements of this standard, so these different in dimensions, physical properties, powder free residue and protein content would not raise new safety concerns.

ITEM	References/Standard	Proposed Device	Predicate Device K210253	Remark
Intended Use	/	Disposable Medical Rubber Examination Gloves are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	SAME
Material	/	Natural Rubber Latex	Natural Rubber Latex	SAME
Color	/	Natural White	Natural Color	SAME
OTC use	/	Yes	Yes	SAME
Single Use	/	Yes	Yes	SAME
Sterile	/	Non-sterile	Non-sterile	SAME
Dimension (Length, Width,Thickness)	ASTM D3578 S-2 AQL 4.0	Length (mm) min Size: Length XS: 230 S: 230 M: 230 L: 230 XL: 230	Length (mm) min Size: Actual value Small: 240 Medium: 240 Large: 240 Extra Large: 241 /: /	Similar
		Width (mm) Size: Width XS: 75±5 S: 85±5 M: 95±5 L: 105±5 XL: 115±5	Width (mm) Size: Actual value Small: 85±10 Medium: 93±10 Large: 105±10 Extra Large: 115±10 /: /	Similar
		Thickness (mm) For all sizes min Finger: 0.08	Thickness (mm) min Size: Palm Actual value: Finger Actual value	Similar

<table>
<tr><td></td><td></td><td>Palm</td><td>0.08</td><td>Small</td><td>0.09</td><td>0.12</td><td></td></tr>
<tr><td></td><td></td><td>/</td><td>/</td><td>Medium</td><td>0.09</td><td>0.12</td><td></td></tr>
<tr><td></td><td></td><td>/</td><td>/</td><td>Large</td><td>0.10</td><td>0.13</td><td></td></tr>
<tr><td></td><td></td><td>/</td><td>/</td><td>Extra Large</td><td>0.09</td><td>0.12</td><td></td></tr>
<tr><td>Physical Properties</td><td>ASTM D412
S-2 AQL 4.0</td><td colspan="3">Type I</td><td colspan="3">Type I</td><td>Similar</td></tr>
<tr><td></td><td></td><td></td><td>Before Aging</td><td>After Accelerated Aging</td><td></td><td>Before Aging</td><td>After Accelerated Aging</td><td></td></tr>
<tr><td></td><td></td><td>Tensile Strength</td><td>18MPa, min</td><td>14 MPa, min</td><td>Tensile Strength</td><td>Size / Actual value</td><td>Size / Actual value</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Small 18.04</td><td>Small 15.02</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Medium 19.13</td><td>Medium 18.12</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Large 18.26</td><td>Large 16.01</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Extra Large 18.64</td><td>Extra Large 15.06</td><td></td></tr>
<tr><td></td><td></td><td>Ultimate Elongation</td><td>650 % min</td><td>500 % min</td><td>Ultimate Elongation</td><td>Size / Actual value</td><td>Size / Actual value</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Small 651</td><td>Small 501</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Medium 654</td><td>Medium 601</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Large 650</td><td>Large 501</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Extra Large 650</td><td>Extra Large 502</td><td></td></tr>
<tr><td>Freedom from holes</td><td>ASTM D5151</td><td colspan="3">No water leakage is inspected.
I AQL 2.5</td><td colspan="3">Pass AQL 2.5</td><td>SAME</td></tr>
<tr><td>Powder Free Residue</td><td>ASTM D6124
N=5
Less than 2.0 mg/glove</td><td colspan="2">Size / Residual powder content (mg/glove)</td><td></td><td colspan="2">Size / Residual powder content (mg/glove)</td><td>Similar</td></tr>
<tr><td></td><td></td><td colspan="2">XS 0.28</td><td></td><td colspan="2">Small 0.62</td><td></td></tr>
<tr><td></td><td></td><td colspan="2">S 0.25</td><td></td><td colspan="2">Medium 0.46</td><td></td></tr>
<tr><td></td><td></td><td colspan="2">M 0.31</td><td></td><td colspan="2">Large 0.61</td><td></td></tr>
<tr><td></td><td></td><td colspan="2">L 0.25</td><td></td><td colspan="2">Extra Large 0.61</td><td></td></tr>
<tr><td></td><td></td><td colspan="2">XL 0.35</td><td></td><td colspan="2">/ /</td><td></td></tr>
<tr><td>Protein Content</td><td>ASTM D5712
N=3
Less than 200 μg/dm^2</td><td colspan="3">Less than 200 μg/dm^2</td><td colspan="3">Protein Content (μg/dm^2)
Size / Actual value
Small 124.36
Medium 140.78
Large 134.26
Extra Large 159.46</td><td>Similar</td></tr>
<tr><td>Cytotoxicity</td><td>ISO 10993-11
The test article showed “negative” systemic toxicity</td><td colspan="3">Under the conditions of the study, the test article showed “negative” systemic toxicity.</td><td colspan="3">Non-cytotoxic</td><td>SAME</td></tr>
<tr><td>Irritation</td><td>ISO 10993-23
The response of the test article has no skin irritation</td><td colspan="3">Under the experimental conditions, the test article has no skin irritation on rabbits.</td><td colspan="3">Non-irritating</td><td>SAME</td></tr>
<tr><td>Sensitization</td><td>ISO 10993-10
The test article showed no evidence of causing delayed dermal contact sensitization.</td><td colspan="3">The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.</td><td colspan="3">Non-sensitizing</td><td>SAME</td></tr>
</table>

9. Summary of Non-Clinical Testing

Bench tests were conducted to demonstrate that the proposed device complies with the following standards:

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 23: Tests for irritation

ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ASTM D3578-19 Standard Specification for Rubber Examination Gloves

Test Item	Test Method	Test Purpose/Description	Acceptance Criteria	Results
Acute Systemic Toxicity Test	Extraction Method	The test was designed to evaluate the potential acute system toxicity caused by test article contact with the ICR mice and extrapolating the results to humans.	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	The test article has no potential acute system toxicity on ICR mice in the extraction method.
Skin Irritation Test	Extraction Method	To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.	ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation.	Under the experimental conditions, the test article has no skin irritation on rabbits.
Skin Sensitization Test	Guinea Pig Maximization	The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.	ISO 10993-10: 2021 Biological Evaluation Of Medical Devices - Part 10: Tests For Skin Sensitization.	Under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the method.
Physical Dimensions Test	Use steel ruler and the apparatus for measurement of thickness (0-10mm) to measure gloves Physical dimensions.	The gloves shall comply with the dimension requirements prescribed in ASTM D3578-19 Table 2.	Inspection Level: S-2 AQL: 4.0	The subject device comply with the dimension requirements prescribed in ASTM D3578-19.

Physical Property Characteristics Test	Dumbbell and Straight Section Specimens.	Before and after accelerated aging, the gloves shall conform to the physical requirements specified in ASTM D3578-19 Table 3.	Inspection Level: S-2 AQL: 4.0	Before and after accelerated aging, the subject device conform to the physical requirements specified in ASTM D3578-19 Table 3.
Freedom From Holes Test	Refer to the ASTM D 5151-06, Standard Test Method for Detection of Holes in Medical Gloves.	This test method is to the detection of holes that allow water leakage under the conditions of the test.	Inspection Level: I AQL: 2.5	No water leakage is inspected. The subject device conform to the requirements specified in ASTM D5151.
Powdered Glove Test	Refer to the ASTM D 6124-06, R2017, Standard Test Method for Residual Powder on Medical Gloves.	These test are the determination of average powder or filter-retained mass found on a sample of medical gloves as described in the introduction.	Inspection Level: N=5 Residual Powder less than 2 mg per glove.	Residual Powder less than 2 mg per glove. The subject device conform to the requirements specified in ASTM D6124.
Extractable Protein Test	Refer to the ASTM D5712 Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method.	The test was designed to test the laechable protein of the test glove.	Inspection Level: N=3 Less than 200 µg/dm^2.	The results showed that the average Extractable Protein of test samples was met the acceptance criteria in ASTM D5712.

10. Summary of Clinical Testing

    Not applicable

11. Conclusions

    Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, BEST GLOVE -LATEX POWDER FREE EXAMINATION GLOVE, cleared under K210253.