March 23, 2023

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

Re: K223895
Trade/Device Name: Disposable Medical Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 28, 2022
Received: December 28, 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 -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
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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)*
K223895

Device Name
Disposable Medical Nitrile Examination Gloves

Indications for Use *(Describe)*
Disposable Medical Nitrile 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.

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K223895 510(k) Summary

1. Date of Preparation: 2023/03/22

2. Submitter

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4. Subject Device Identification

510(k) Number: K223895

Trade Name: Disposable Medical Nitrile Examination Gloves

Common Name: Polymer Patient Examination Glove

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

5. Predicate Device Identification

510(k) Number: K222498

Product Name: Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)

Manufacturer: Humanwell Healthcare Group Medical Supplies Co., Ltd

Regulatory Information:

Classification: I

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Common Name: Polymer Patient Examination Glove

6. Device Description

The Disposable Medical Nitrile Examination Gloves are manufactured to meet the all current specifications listed under the ASTM Specification D6319 - 19, Standard Specification for Nitrile Examination Gloves for Medical Application. Disposable Medical Nitrile Examination Gloves are mainly composed of nitrile latex. It is mainly suitable for hand protection during medical examination. These gloves are powder free.
The proposed device(s) are orange color and sold non-sterile and are intended to be single-use, disposable devices.

7. Indication For Use Statement

Disposable Medical Nitrile 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

Table 1 General Comparison

ITEM	Proposed Device (K223895) Disposable Medical Nitrile Examination Gloves	Predicate Device (K222498) Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)	Remark
Product Code	LZA	LZA	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Intended Use	Disposable Medical Nitrile Examination Gloves are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Medical Examination Glove (Nitrile) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	SAME
Powder free	Yes	Yes	SAME

Design feature	Ambidextrous	Ambidextrous	SAME
Material	Nitrile	Nitrile	SAME
OTC use	Yes	Yes	SAME
Sterility	Non-sterile	Non-sterile	SAME
Use	Singe use	Singe use	SAME
Label	Single-use, indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder Free orange, Non-Sterile	Single-use, indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder Free Blue, Non-Sterile	SAME

Table 2 Device Dimensions Comparison

Proposed Device (K223895) Disposable Medical Nitrile Examination Gloves	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.1					±0.03
	Palm	0.08					±0.03
	Cuff	0.07					±0.03
Predicate Device (K222498) Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	220	220	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
	Cuff	unavailable					min
Remark	Similar						

Analysis:
The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D 6319. So the difference does not affect the substantial equivalence in effectiveness and safety.

Table 3 Performance Comparison

ITEM			Proposed Device (K223895) Disposable Medical Nitrile Examination Gloves	Predicate Device (K222498) Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)	Remark
Colorant			Orange	Blue	Different
Physical Properties	Before Aging	Tensile Strength	14 MPa, min	14 MPa, min	SAME
		Ultimate Elongation	500 % min	500 % min	SAME
	After Aging	Tensile Strength	14 MPa, min	14 MPa, min	SAME
		Ultimate Elongation	400 % min	400 % min	SAME
	Comply with ASTM D6319			Comply with ASTM D6319	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 G-1, AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 G-1, AQL 1.5	SAME
Residual Powder			Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	SAME

Analysis:
The subject device has different colour to the predicate device. The colour of the proposed device is orange and predicate device is Blue. But the Biocompatibility testing was successfully completed for the subject device, demonstrating that the difference does not affect the substantial equivalence in effectiveness and safety.

Table 4 Safety Comparison

ITEM		Proposed Device (K223895) Disposable Medical Nitrile Examination Gloves	Predicate Device (K222498) Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	SAME
	Sensitization	Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	
	acute systemic toxicity	Under the conditions of the study, there was no evidence of systemic toxicity from the extract.	Under the conditions of the study, there was no evidence of systemic toxicity from the extract.	SAME
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	SAME

Analysis:

We have conducted the testing according to the ISO10993-1, Acute Systemic Toxicity, irritation and sensitization. The test results shown that no biocompatibility risk would be raised. So, we consider that the proposed device has same biocompatibility performance with the predicate device.

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 D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D6124-06 (R2017) Standard Test Method for Residual Powder on Medical Gloves

ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves

Table 5 Bench Tests Summary

Title of the test	Purpose of the test	Acceptance criteria and the source of references	Results
Physical Dimensions	Detection of the conformity that whether the gloves whether the dimension requirements prescribed in ASTM 6319-19 Table 2.	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves.	The subject device complies with the dimension requirements prescribed in ASTM D6319-19.
Physical Property Characteristics	Detection of the conformity that whether the gloves meet the requirements specified in ASTM D6319-19 Table 3, before and after accelerated aging.	ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension	Before and after accelerated aging, the subject device complies with the physical requirements specified in ASTM D6319-19 Table 3.
Freedom From Holes	Detection of holes that allow water leakage under the conditions of the test.	ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves.	No water leakage is inspected. The subject device complies with the requirements specified in ASTM D5151.
Residual	Determine the amount of	Residual Powder less	Residual Powder less than

Powder	residual powder found on a sample of medical gloves.	than 2 mg per glove as required in ASTM D 6124-06, R2017, Standard Test Method for Residual Powder on Medical Gloves.	2 mg per glove. The subject device complies with the requirements specified in ASTM D6124.
Acute Systemic Toxicity	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	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	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.	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

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, Medical Examination Gloves (Nitrile) (XS, S, M, L, XL), cleared under K222498.