April 4, 2024

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: K240361
Trade/Device Name: Power Free Green Nitrile Examination Gloves (XS/S/M/L/XL); Power Free Pink Nitrile Examination Gloves (XS/S/M/L/XL); Power Free Purple Nitrile Examination Gloves (XS/S/M/L/XL)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 6, 2024
Received: February 6, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K240361

Device Name

Powder Free Green Nitrile Examination Gloves (XS/S/M/L/XL);
Powder Free Pink Nitrile Examination Gloves (XS/S/M/L/XL); Powder
Free Purple Nitrile Examination Gloves (XS/S/M/L/XL)

Indications for Use *(Describe)*

Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands 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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510(k) Summary

The assigned 510(k) Number: K240361

1. Date of Preparation: 03/13/2024

2. Submitter

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4. Subject Device Identification

Trade Name: Powder Free Green Nitrile Examination Gloves
Powder Free Pink Nitrile Examination Gloves
Powder Free Purple Nitrile Examination Gloves

Common Name: Medical 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: K232008

Product Name: Disposable Medical Examination Nitrile Gloves

Manufacturer: Longgang City Ailiya Arts Crafts Co., Ltd.

Regulatory Information:

Classification: I

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Common Name: Medical examination gloves

6. Device Description

Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple 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. Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple 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 difference between the devices is the color: the color of powder free green nitrile examination gloves is green, the color of powder free pink nitrile examination gloves is pink, the color of powder free purple nitrile examination gloves is purple.

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

7. Indication For Use Statement

Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

8. Technological Characteristic Comparison Summary

Table 1 Comparison of Technology Characteristics

ITEM		Proposed Device (K240361) Powder Free Green/Pink/Purple Nitrile Examination Gloves	Predicate Device (K232008) Disposable Medical Examination Nitrile Gloves	Remark
Product Code		LZA	LZA	SAME
Regulation No.		21 CFR 880.6250	21 CFR 880.6250	SAME
Class		I	I	SAME
Intended Use / Indications for Use		Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner ' s hands to prevent contamination between patient and examiner.	The Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	SAME
Powder free		Yes	Yes	SAME
Design feature		Ambidextrous	Ambidextrous	SAME
Material		Nitrile	Nitrile	SAME
Color		Green, Pink, Purple	Black	Different 1
OTC use		Yes	Yes	SAME
Sterility		Non-sterile	Non-sterile	SAME
Use		Singe use	Singe use	SAME
Labeling Information		Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile.	Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile.	SAME
Size and Dimensions (mm)		Length (mm): XS/S/M/L/XL: ≥230 Width(mm): XS: 70±10mm; S: 85±10mm; M: 95±10mm; L: 110±10 mm; XL: 120±10 mm	Length (mm): XS/S: ≥220; M/L/XL/XXL: ≥230; Width(mm): XS: 70±10mm; S: 80±10mm; M: 95±10mm; L: 110±10 mm; XL: 120±10 mm; XXL: 130±10 mm	Different 2
Thickness (mm)		Finger: ≥0.05; Palm: ≥0.05	Finger: ≥0.05; Palm: ≥0.05	SAME
Physical Properties	Before Aging	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	SAME
		Ultimate Elongation:500% min	Ultimate Elongation:500% min	SAME
	After Aging	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	SAME
		Ultimate Elongation:400% min	Ultimate Elongation:400% min	SAME
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151	Be free from holes when tested in accordance with ASTMD5151	SAME
Powder Content		Meet the requirements of ASTM D6124 Less than 2mg per glove	Meet the requirements of ASTM D6124 Less than 2mg per glove	SAME
Biocompatibility		ISO 10993-10, under the conditions of the study, not a sensitizer	ISO 10993-10, under the conditions of the study, not an irritant or a sensitizer	SAME
		ISO 10993-23, under the conditions of the study, not an irritant		
		ISO 10993-11, under the condition of acute systemic toxicity test, the test article did not show acute	ISO 10993-11, under the condition of acute systemic toxicity test, the test article did not show acute	SAME

	systemic toxicity in vivo.	systemic toxicity in vivo.	

Different 1-Color

The color of the proposed device is different from the predicate device. However, the biocompatibility and specification performance tests have been performed on each of the proposed devices and the test results show no significant concerns. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different 2-Size and dimension

The size and dimension of the proposed device is not exactly same as the predicate device. However, the size and dimension of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user's hand. In addition, its dimension has been tested and met the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated 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 10993-11:2017 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 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D412-16(2021) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension

Table 2 Summary of non clinical performance testing

Test Method	**Purpose**	**Acceptance Criteria**	**Results**
ASTM D6319-19	Physical Dimensions Test	Length (mm): XS/S/M/L/XL: ≥230 Width(mm): XS: 70±10mm; S: 85±10mm; M: 95±10mm; L: 110±10 mm; XL: 120±10 mm	Length(mm):XS/S/M/L/XL:236~239 Pass Width(mm):XS 70; S 85~86;M 95~96;L110~112;XL 120 Pass
		Thickness (mm): Finger: ≥0.05; Palm: ≥0.05	Finger:0.23~0.47 Palm: 0.26~0.46

				Pass
ASTM D5151-19	Watertightness Test for Detection of Holes	Be free from holes when tested in accordance with ASTM D5151		Pass
ASTM D412	Physical Properties	Before Aging	Tensile Strength: 14MPa, min	20.16~28.78MPa/Pass
			Ultimate Elongation:500% min	522~558MPa/Pass
		After Aging	Tensile Strength: 14MPa, min	18.25~20.39MPa/Pass
			Ultimate Elongation:400% min	525~555MPa/Pass
ASTM D6124	Powder Content	Meet the requirements of Less than 2mg per glove		≤0.46mg/Pass
ISO 10993-10	Irritation	Non-irritating		Under the conditions of the study, not an irritant.
ISO 10993-11	Acute systemic toxicity	Non- acute systemic toxicity		Under conditions of the study, did not show acute systemic toxicity in vivo.
ISO 10993-23	Sensitization	Non-sensitizing		Under the conditions of the study, not a sensitizer.

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, Disposable Medical Examination Nitrile Gloves, cleared under K232008.