October 28, 2021

Leping Shengde Medical Technology Company Limited
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K211581
Trade/Device Name: Disposable Nitrile Examination Gloves (Powder free, Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 30, 2021
Received: October 6, 2021

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,

For Clarence W. Murray, III, 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)*

K211581

Device Name

DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)

Indications for Use *(Describe)*

The DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue) 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

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K211581

1. Date of Preparation: 10/28/2021

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)
Common Name: NITRILE Patient Examination Gloves (Powder Free)
Regulatory Information:
Classification: I
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication For Use Statement:
The DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

Primary Predicate Device
510(k) Number: K150340
Product Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)
Manufacturer: HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD

Reference Device
510(k) Number: K210898
Product Name: Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue)
Manufacturer: Tangshan Lanhai Medical Supplies Co., Ltd.

6. Device Description

The proposed device, DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue) are disposable devices intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

The proposed devices are Powder Free Nitrile Examination Gloves and includes variations of different size. The color of the proposed device is Blue.

The proposed device is not provided as sterilized
The proposed device is made of Nitrile.

Table 1 Device Size Specifications

Size Model	Cuff Thickness (mm)	Palm Thickness (mm)	Finger Thickness (mm)	Width (mm)	Length (mm)	Color
S	≥ 0.05	≥ 0.05	≥ 0.05	80±10	≥ 220	Blue
M	≥ 0.05	≥ 0.05	≥ 0.05	95±10	≥ 230	
L	≥ 0.05	≥ 0.05	≥ 0.05	110±10		
XL	≥ 0.05	≥ 0.05	≥ 0.05	120±10		

Table 2 Performance and Physical Specifications

Before Aging		After Aging		Pinhole AQL
Tensile	Ultimate	Tensile	Ultimate	1.5

Strength	Elongation	Strength	Elongation	
14 MPa, min	500 % min	14 MPa, min	400 % min	

The above data of size, performance, and physical specifications of proposed gloves meet all the current specifications listed in the ASTM standard D6319.

7. Comparison of technological characteristics between the subject and predicate devices

Table 1 General Comparison

ITEM	Proposed Device DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Remark
Product Code	LZA	LZA	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Intended Use	The DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	SAME
Powdered or Powered free	Powdered free	Powdered free	SAME

Table 2 Device Dimensions Comparison

Proposed Device DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	220	230	230	230	min
	Width, mm	80	95	110	120	±10
	Thickness, mm:					
	Finger	0.05				min
	Palm	0.05				min
	Cuff	0.05				min
Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	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	0.10-0.12					±0.03
	Palm	0.08-0.10					±0.03
	Cuff	0.06-0.09					±0.03
Reference Device DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	220	230	230	230	min
	Width, mm	80	95	110	120	±10
	Thickness, mm:					
	Finger	0.05				min
	Palm	0.05				min
	Cuff	0.05				min
Remark	Similar					

Different Analysis:

The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D 6319.

Table 3 Performance Comparison

ITEM	Proposed Device DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Reference Device (K210898) DISPOSABLE NITRILE EXAMINATION	Remark

					GLOVES (Powder free, Blue)	
Colorant			Blue	White, Cobalt Blue, Black, Ice Blue	Purple-Blue, Blue	Different
Physical Properties	Before Aging	Tensile Strength	14 MPa, min	15 MPa, min	14 MPa, min	Different
		Ultimate Elongation	500 % min	500 % min	500% min	SAME
	After Aging	Tensile Strength	14 MPa, min	14 MPa, min	14 MPa min	SAME
		Ultimate Elongation	400 % min	400 % min	400% min	SAME
	Comply with ASTM D6319			Comply with ASTM D6319	Comply with ASTM D6319	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 AQL 2.5	SAME
Powder Content			Less than 2 mg per glove when tested in accordance with ASTM D6124	Meet the requirements of ASTM 6124	Meet the requirements of ASTM 6124	SAME

Different Analysis:

The proposed device has different color to the predicate device, this different may causes potential biocompatibility risk, for this risk we conducted the biocompatibility test according to the ISO 10993-10 and ISO 10993-11 and the test results showed that the proposed devices did not induce skin irritation and showed no significant evidence of causing skin sensitization and systemic toxicity response.

Different Analysis:

The proposed device has different Tensile Strength before aging specification to the predicate device, but all proposed device meets the specification requirements of ASTM D 6319.

Table 4 Safety Comparison

ITEM		Proposed Device DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Reference Device (K210898) DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue)	Remark
Material		Nitrile	Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	SAME
	Sensitization	Under conditions of the	Under conditions of the study,	Under conditions of the	

		study, not a sensitizer.	not a sensitizer.	study, not a sensitizer.	
	acute systemic toxicity	Under the conditions of the study, there was no evidence of systemic toxicity from the extract.	Not Available	Under the conditions of the study, there was no evidence of systemic toxicity from the extract.	Different
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements	SAME

Different Analysis:
The proposed device has conducted the acute systemic toxicity testing, and the test results showed that there was no evidence of systemic toxicity.

8. Summary of Non-Clinical Testing

Bench 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:

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-17, Standard Test Method for Residual Powder on Medical Gloves.
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Table 5 Performance Test Results Summary

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151	Testing for Freedom from holes	Freedom from holes AQL 2.5	No water leakage is inspected form 200 samples
ASTM D6124	Determine the powder residue for powder free gloves	<2.0 mg per glove	Residual Powder of Size S: Average 0.36 mg; Residual Powder of Size M: Average 0.37 mg; Residual Powder of Size L: Average 0.34 mg; Residual Powder of Size XL: Average 0.32mg;
ASTM D412 ASTM D573	Testing for Physical property characteristics	Before Aging Tensile Strength: 14 MPa min. Ultimate Elongation: 500% min. Before Aging Tensile Strength: 14 MPa min. Ultimate Elongation: 400% min.	Before Aging Tensile Strength: ≥ 19MPa; Ultimate Elongation: ≥ 500%. After Aging Tensile Strength: ≥ 18 MPa; Ultimate Elongation: ≥ 472%.
ASTM D412 ASTM D3767	Testing For physical dimensions specification	Length: 220 mm min. for size (S); Length: 230 mm min. for size (M，L, XL); 80±10 mm for S; 95±10 mm for M;	Length of Size S: ≥ 223mm; Width of Size S: 85±2 (85-87) mm; Cuff Thickness of Size S: ≥0.06 mm; Palm Thickness of Size S: ≥0.07 mm;

		110±10 mm for L; 120±10 mm for XL. Cuff Thickness: ≥0.05 mm; Finger Thickness: ≥0.05 mm; Palm Thickness: ≥0.05 mm; All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319	Finger Thickness of Size S: ≥0.10 mm. Length of Size M: ≥ 231 mm; Width of Size M: 95±3 (95-97) mm; Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 231mm; Width of Size L: 107±2 (105-109) mm; Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 233mm; Width of Size XL: 121±6 (115-127) mm; Cuff Thickness of Size XL: ≥0.06 mm; Palm Thickness of Size XL: ≥0.07 mm; Finger Thickness of Size XL: ≥0.10 mm.
ISO 10993-11	Evaluate the endpoint of Cytotoxicity for biocompatibility	The test article showed no evidence of cytotoxic potential from the extract.	The test article showed no evidence of systemic toxicity from the extract.
ISO 10993-10	Evaluate the endpoint of irritant for biocompatibility	The response of the test article extract is negligible.	The test result showed that the response of the test article extract was categorized as negligible under the test condition.
	Evaluate the endpoint of sensitization for biocompatibility	The test article showed no evidence of causing delayed dermal contact sensitization.	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

9. Summary of Clinical Testing

Clinical Testing is not applicable.

10. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) cleared under K150340.