July 10, 2021

Jiangxi Hongda Medical Equipment Group 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, Beijing 102401
China

Re: K210578
Trade/Device Name: Medical Nitrile Examination Gloves (Power free, Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 9, 2021
Received: April 13, 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,

Jiangsong Jiang -S
(Affiliate)

For Ryan Ortega
Acting 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)*
K210578

Device Name
Medical Nitrile Examination Gloves (Powder free, Blue)

Indications for Use *(Describe)*
The Medical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K210578

1. Date of Preparation: 07/09/2021

2. Sponsor

Jiangxi Hongda Medical Equipment Group Ltd.
No. 39 South Shengli Road, Jinxian County, Nanchang City, JiangXi Province, 331700, China
Contact Person: Yang Qinghua
Position: Manager
Tel: +86-18970093059
Fax: +86-791-85628888
Email: zkb@jxhd.cn

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

Tel: +86-18910677558
Fax: +86-10-56335780
Email: ray.wang@believe-med.com

4. Proposed Device Identification

Trade Name: Medical 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

5. Predicate Device Identification

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

6. Device Description

The proposed device is Powder Free Nitrile Examination Gloves and has different size specification and color.
The proposed device is provided in non-sterile.
The proposed device is made of Nitrile.
The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D6319

Table 1 Device Size Specifications

Size Model	Cuff Thickness (mm)	Palm Thickness (mm)	Finger Thickness (mm)	Width (mm)	Length (mm)	Color
XS	≥ 0.05	≥ 0.05	≥ 0.05	70±10	≥ 220	Blue
S	≥ 0.05	≥ 0.05	≥ 0.05	80±10		
U	≥ 0.05	≥ 0.05	≥ 0.05	85±10	≥ 230	
M	≥ 0.05	≥ 0.05	≥ 0.05	95±10		
L	≥ 0.05	≥ 0.05	≥ 0.05	110±10		
X-L	≥ 0.05	≥ 0.05	≥ 0.05	120±10		
XX-L	≥ 0.05	≥ 0.05	≥ 0.05	130±10		

Table 2 Performance and Physical Specifications

Before Aging		After Aging		Pinhole AQL
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation	2.5
14 MPa, min	500 % min	14 MPa, min	400 % min	

7. Indications for Use: The proposed device, Medical 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.

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

Table 1 General Comparison

ITEM	Proposed Device Medical 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

Indications For Use	The Medical 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 Powder free	Powder free	Powder free	SAME

Table 2 Device Dimensions Comparison

Proposed Device Medical Nitrile Examination Gloves (Powder free, Blue)	Designation	Size							Tolerance
		XS	S	U	M	L	XL	XXL	
	Length, mm	220	220	230	230	230	230	230	min
	Width, mm	70	80	85	95	110	120	130	±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
Remark	Analysis 1						

Analysis 1:

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

So we consider this as the proposed device is same with the predicate device.

Table 3 Performance Comparison

ITEM	Proposed Device Medical Nitrile Examination Gloves (Powder free, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Remark
Colorant	Blue	White, Cobalt Blue, Black, Ice Blue	Analysis 2

Physical Properties	Before Aging	Tensile Strength	14 MPa, min	15 MPa, min	Analysis 3
		Ultimate Elongation	500 % min	500 % min	SAME
	After Aging	Tensile Strength	14 MPa, min	14 MPa, min	SAME
		Ultimate	400 % min	400 % min	SAME
		Elongation			
	Comply with ASTM D6319			Comply with ASTM D6319	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	SAME
Powder Content			Less than 2 mg per glove when tested in accordance with ASTM D6124	Meet the requirements of ASTM D6319	SAME

Analysis 2:

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, the test results showed that the proposed devices with blue colorant did not induce skin irritation and showed no significant evidence of causing skin sensitization.

So we consider this as the proposed device is SE with the predicate device.

Analysis 3:

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.

So we consider this as the proposed device is SE with the predicate device.

Table 4 Safety Comparison

ITEM		Proposed Device Medical Nitrile Examination Gloves (Powder free, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study (ISO 10993-10), not an irritant	Under the conditions of the study, not an irritant	SAME
	Sensitization	Under conditions of the study (ISO 10993-10), not a sensitizer.	Under conditions of the study, not a sensitizer.	
	Acute Systemic Toxicity	Under the condition of the study (ISO 10993-11), there is no mortality or evidence of systemic toxicity	/	Analysis 4
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	SAME

Analysis 4

The proposed device has conducted the testing of Acute Systemic Toxicity which is the predicate device did not, the testing results shown that the proposed device has no systemic toxicity.

9. Summary of Non-Clinical Performance Tests

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. 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.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210578, the Medical Nitrile Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K150340.