August 20, 2021

Beijing Biosis Healing Biological Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K203622
Trade/Device Name: Medical Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 10, 2021
Received: July 19, 2021

Dear Diana Hong:

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)*
K203622

Device Name
Medical Gloves

Indications for Use *(Describe)*
A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K203622

1. Date of Preparation: 08/19/2021

2. Sponsor Identification

Beijing Biosis Healing Biological Technology Co., Ltd.
No.6 Plant West, Valley No.1 bio-medicine Industry Park, Daxing District, Beijing, 102600, China.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Medical Gloves
Common Name: Patient Examination Glove

Regulatory Information
Classification Name: Non-powderedpatient examination glove
Classification: I;
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for use:

A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Device Description:

The proposed device is a powder free medical glove. The device is made from a nitrile latex compound, blue in color. The device meets the requirements of ASTM D6319-19: Standard specification for Nitrile Examination Gloves for Medical Application. The device is available in five sizes, which are XS, S, M, L, XL, it could be selected by the user depended on size of hand. The different between each size is just in the dimension. The device can be provided in non-sterile.

5. Identification of Predicate Device

510(k) Number: K180467
Product Name: SBG Blue Nitrile Powder Free Medical Examination Glove

6. Technological Comparison:

Table 1 General
Technological Comparison

ITEM	Proposed Device K203622	Predicate Device K180467	Remark
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	Class Ⅰ	Class Ⅰ	Same
Indication for use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers 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 hands or fingers to prevent contamination between patient and examiner.	Same
Material	Nitrile latex compound	Nitrile latex compound	Same
Color	Blue	Blue	Same
Sterility	Non-sterile	Non-sterile	Same
Model	XS, S, M, L, XL	S, M, L, XL	Analysis 1
Dimensions (ASTM D6319-19)	> 220 mm (XS and S sizes) > 230 mm (M, L and XL sizes)	Overall Length (mm) 220 mm = (sizes XS-S) 230 mm = (sizes M-XL)	Analysis 2
	Width(±10mm) XS = 70mm S = 80mm M = 95mm L = 110mm XL = 120mm	Width (± 10 mm) Size S = 80 mm Size M = 95 mm Size L = 110 mm Size XL = 120 mm	
	Thickness at Finger (mm) All Sizes ≥ 0.05 mm	Thickness at Finger (mm) All Sizes = 0.05 mm	
	Thickness at Palm All Sizes ≥ 0.05 mm	Thickness at Palm All Sizes = 0.05 mm	
Physical Properties (ASTM D6319-19 and ASTM D412-16)	Before Aging Tensile Strength ≥ 14Mpa Ultimate Elongation ≥ 500% After Aging Tensile Strength ≥ 14Mpa Ultimate Elongation ≥ 400%	Before Aging Tensile Strength ≥ 14Mpa Ultimate Elongation ≥ 500% After Aging Tensile Strength ≥ 14Mpa Ultimate Elongation ≥ 400%	Analysis 3

Powder free residue (ASTM D6319-19 and ASTM D6124-06)	Less than 2 mg per glove	Less than 2 mg per glove	Analysis 4
Freedom from Holes (ASTM D5151-19)	AQL 2.5 Inspection Level G-1 Accept at 5 failures Reject at 6 failures Meets ASTM D5151-19	AQL 2.5 Inspection Level G-1 Accept at 5 failures Reject at 6 failures Meets ASTM D5151-06	Analysis 5
Skin Irritation	No Irritation	No Irritation	Same
Sensitization	No Sensitization	No Sensitization	Same
Acute toxicity	No acute toxicity	/	Analysis 6

Analysis 1 - Model

The proposed device has the additional XS size compared to predicate device. A various sizes could provide more choices for users and the different size does not affect intended use. In addition, the size XS of proposed device has been tested and the test result demonstrated that it could meet the requirements of ASTM D6319-19. Therefore, it can be considered that this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 2 - Dimensions

The dimensions of proposed device are different from predicate device 1. The proposed device has one more XS size and the minimum length of proposed device is larger than the predicate device 1. In addition, the proposed device was tested according to the ASTM D6319-19 while the predicate device 1 was tested according to ASTM D6319-10. However, these two standards are just different in version and all test results of dimensions for proposed device could met the requirements of ASTM D6319 -19. Therefore, it can be considered that this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 3 - Physical Properties

The standard version of Physical Properties requirements for the proposed device is different from the predicated device 1. The proposed device was tested and met the requirements of ASTM D6319 -19 while the predicate device 1 was tested and met the requirements of ASTM D6319-10. However, these two standards are just different in version. Therefore, it can be considered that this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 4 - Powder free residue

The standard version of Powder free residue requirements for the proposed device is different from the predicated device 1. The proposed device was tested and met the requirements of ASTM D6319 -19 while the predicate device 1 was tested and met the requirements of ASTM D6319-10. However, these two standards are just different in version. Therefore, it can be considered that this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 5 - Freedom from Holes

The standard version of Freedom from Holes requirements for the proposed device is different from the predicated device 1. The proposed device was tested and met the requirements of ASTM D5151 -19 while the predicate device 1 was tested and met the requirements of ASTM D5151-06. However, these two standards are just different in version. Therefore, it can be considered that this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 6-Biocompabitlity

The contact level and duration for the proposed device is intact skin and limited contact. Cytotoxicity, Skin sensitization and irritation shall be evaluated for the proposed device per FDA guidance. Acute toxicity test was evaluated for the proposed device instead of cytotoxicity. The test result showed that there was no adverse effect. Therefore, it can be considered that the proposed device is safety as the predicate device.

7. Non-Clinical Testing:

Non clinical tests were conducted to provide data that the proposed devices met the acceptance criteria or the specification for the test methodology or standard shown below. The test results demonstrated that the proposed devices comply 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 D3767-03 Standard Practice for Rubber-Measurement of Dimensions
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
- ASTM D6124-06 (Reapproved 2017) 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;

Test Method	Purpose	Acceptance Criteria	Results
Freedom from Holes-ASTM D5151	Detection the holes that allow water leakage	Do not show droplet, stream or other type of water leakage	No leakage
Physical dimension-ASTM D6319	Evaluate the glove physical dimension	Length: >220 mm (XS and S sizes) Length: > 230 mm (M, L and XL sizes) Width (±10mm) XS = 70mm S = 80mm M = 95mm L = 110mm XL = 120mm Thickness at Finger (mm) All Sizes ≥ 0.05 mm Thickness at Palm All Sizes ≥ 0.05 mm	Length Larger than 220mm for XS and S size Larger than 230mm for M, L and XL sizes Width XS: within 70±10mm S: within 80±10mm M: within 95±10mm L: within 110±10mm XL: within 120±10mm Thickness Larger than 0.05mm
Physical requirement-ASTM D412	Evaluate the physical requirement	Before Aging (Min) Tensile strength: 14Mpa Ultimate elongation: 500% After Aging (Min) Tensile strength: 14Mpa Ultimate elongation: 400%	Before aging Larger than 14Mpa and 500% After aging Larger than 14Mpa and 400%
Powder residue-ASTM D6214	Evaluate the residue powder	Less than 2.0mg	Less than 2.0mg
Skin sensitization-ISO 10993-10	Evaluated for the potential to cause delayed dermal contact sensitization	Magnusson and Kligman grade shall be less than control group	No skin sensitization
Skin irritation-ISO 10993-10	Evaluated for the potential to cause skin irritation	No significant reaction than the control group	No skin irritation
Acute toxicity-ISO 10993-11	Evaluated for acute systemic toxicity	No significant reaction than the control group Animal death or abnormal behaviour no more than two animals Body weight loss greater than 10% no more than 3 animals	No acute toxicity

8. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K203622, the Medical Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180467.