May 31, 2023

Huizhou Anboson Technology Co., Ltd.
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K230542
Trade/Device Name: Disposable Nitrile Gloves (ABC-DG01)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 5, 2023
Received: May 5, 2023

Dear Ivy 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
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)*
K230542

Device Name
Disposable Nitrile Gloves (ABC-DG01)

Indications for Use *(Describe)*
The Disposable Nitrile Glove is a disposable device intended for medical purposes 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.

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

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510(K) Summary

(As requirement by 21 CFR 807.92)

K230542

Date prepared: 2023-05-05

A. Applicant:

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B. Device:

Trade Name: Disposable Nitrile Gloves
Common Name: Nitrile Patient Examination Gloves (Powder Free) Model: ABC-DG01

Regulatory Information
Classification Name: Non-powdered patient examination glove
Classification: Class I
Product code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device:

K171422
Disposable Powder Free Nitrile Examination Glove, White/Blue/ Black/ Pink Color
Ever Global (Vietnam) Enterprise Corp

D. Indications for use of the device:

The Disposable Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

E. Device Description:

The Disposable Nitrile Gloves are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are blue or black color, powder free, nitrile ambidextrous gloves. The gloves are offered in large (L) size, packed in a paper box.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard.

F. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	K230542	K171422	-
Product Name	Disposable Nitrile Gloves	Disposable Powder Free Nitrile Examination Glove, White/Blue/ Black/ Pink Color	-
Product Code	LZA	LZA	Same
Classification	Class I	Class I	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	The Disposable Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color 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
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Singe use	Single use	Same
Label	Single-use, indication, powder free, device color, device name, glove size and quantity, Disposable Nitrile Glove, Non-Sterile	Single-use, indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove, Non-Sterile	Same

Table 2 Device dimension comparison

Predicate device	Designation	Size					Tolerance
		XS	S	M	L	XL	

(K171422)	Length, mm	230	230	230	230	230	min
	Width, mm	75	85	90	105	115	±5
	Thickness, mm						
	Finger	0.05					min
	Palm	0.05					min
Proposed device K230542	Designation	Size					Tolerance
		L					
	Length, mm	230					min
	Width, mm	110					±10
	Thickness, mm						
	Finger	0.05					min
	Palm	0.05					min
Result	Similar						

Analysis: The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D6319-19, so the differences do not raise any new safety or performance questions.

The proposed device has less size than that of the predicate device, while this difference will not affect the safety or performance of the proposed device.

Table 3 Performance comparison

Item			**Proposed device (K230542)**	**Predicate device (K171422)**	**Result**
Colorant			Blue/ Black	White/ Blue/ Black/ Pink	Similar
Physical properties	Before aging	Tensile strength	14MPa, min	14MPa, min	Same
		Ultimate elongation	500%, min	500%, min	Same
	After aging	Tensile strength	14MPa, min	14MPa, 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 2.5	Be free from holes when tested in accordance with ASTM D5151 G-1, AQL 2.5	Same
Residual Powder			Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	Same

Analysis: The subject device is available in blue or black color; however, the predicate is available in multiple colors (white, blue, black, pink). Biocompatibility testing was successfully completed for the subject device, demonstrating that any color differences do not affect the safety of the proposed device.

Table 4 Biocompatibility comparison

Item		Proposed device (K230542)	Predicate device (K171422)	Result
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation ISO 10993-23	Under the conditions of the study, not an irritant.	Comply with ISO 10993-10	Same
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer.		
	In Vitro Cytotoxicity ISO 10993-5	Under the conditions of the study, the test article extract showed potential toxicity.	Not available	Different
	Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Not available	Different

Analysis: In vitro cytotoxicity and acute systemic toxicity information for the predicate device is not publicly available. This does not raise different safety or performance questions since the subject device has acceptable biocompatibility per the biocompatibility endpoint assessment.

G. Summary of Non-Clinical Testing

➢ **Biocompatibility**

The following tests for the subject device were conducted to evaluated the biocompatibility of Disposable Nitrile Gloves:

- ISO 10993-5: In Vitro Cytotoxicity
- ISO 10993-23: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Acute Systemic Toxicity

➢ **Performance Testing**

Performance testing of the proposed device was conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*.

To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- 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

Test Method	Purpose	Acceptance Criteria	Results (Blue & Black)
Dimensions (width) (thickness) ASTM D6319-19	The purpose of the test is to evaluate the physical dimension of the glove	Width 110 ±10mm Length 230mm min	Pass 106mm min width 250mm min length
		Palm – 0.05mm min. Finger–0.05mm min.	Pass Palm – 0.06mm min. Finger–0.12mm min
Physical properties ASTM D6319-19	The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging	Tensile Strength: Before Aging ⩾ 14 MPa, min. After Aging ⩾ 14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Pass Tensile Strength: Before Aging 19.07MPa, min. After Aging 18.11 MPa, min. Elongation: Before Aging 586.47%, min. After Aging 469.20%, min.
Freedom from holes ASTM D5151-19	The purpose of the test is to detect holes in the gloves	No leakage at sampling level of G-1, AQL 2.5	Pass No leakage, 125 of 125 passed of each color
Residual Powder ASTM D6124-06 (Reapproved 2017)	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass average 0.07 mg per glove

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Disposable Nitrile Gloves are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K171422.