October 26, 2022

Humanwell Healthcare Group Medical Supplies Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th F, 1500# Century Avenue
Shanghai, 200122
China

Re: K222498
Trade/Device Name: Medical Examination Gloves (Nitrile) (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: August 18, 2022
Received: August 18, 2022

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, M.D., 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.

Submission Number *(if known)*

K222498

Device Name

Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)

Indications for Use *(Describe)*

The Medical Examination Glove (Nitrile) 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.

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K222498

510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 2022-10-25

A. Applicant:

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B. Device:

Trade Name: Medical Examination Gloves (Nitrile) (XS, S, M, L, XL)
Common Name: Nitrile Patient Examination Gloves (Powder Free)

Regulatory Information
Classification Name: Polymer 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 Medical Examination Glove (Nitrile) 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 Medical Examination Gloves (Nitrile) 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 color, powder free, nitrile ambidextrous gloves. The gloves are offered in sizes extra-small, small, medium, large, extra-large 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 #	K222498	K171422	-
Product Name	Medical Examination Gloves (Nitrile)	Disposable Powder Free Nitrile Examination Glove, White/Blue/ Black/ Pink Color	-
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	The Medical Examination Glove (Nitrile) 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, Nitrile Glove Powder Free Blue, 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 (K171422)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	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	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	220	220	230	230	230	min
	Width, mm	70	80	95	110	120	±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.

Table 3 Performance comparison

Item			**Proposed device**	**Predicate device (K171422)**	**Result**
Colorant			Blue	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 only available in a single color (blue,) 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**	**Predicate device (K171422)**	**Result**
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation ISO 10993-10	Under the conditions of the	Comply with ISO 10993-10	Same

		study, not an irritant. Comply with ISO 10993-10.		
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10.		
	Acute systemic toxicity ISO 10993-11	Under the conditions of the study, the device is non-toxic.	/	Different

Analysis: 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 Medical Nitrile Examination Gloves:

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Acute Systemic Toxicity

Test	Purpose	Acceptance Criteria	Results
Irritation ISO 10993-10	The purpose of the test is to verify that the proposed device extract is non-irritating.	Under the conditions of the study, not an irritant.	Pass
Sensitization ISO 10993-10	The purpose of the test is to verify that the proposed device extract is non-sensitizing	Under the conditions of the study, not a sensitizer.	Pass
Acute systemic toxicity ISO 10993-11	The purpose of the test is to verify that the proposed device extract is non-cytotoxic.	Under the conditions of the study, the device is non-toxic.	Pass

➢ **Performance Testing**

Physical 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
Dimensions (width) (thickness)	The purpose of the test is to evaluate the physical dimension of the glove	Width 70mm min Length 220mm min	Pass 76mm min width 234mm min length
		Palm – 0.05mm min. Finger–0.05mm min.	Pass Palm – 0.08mm min. Finger–0.09mm min
Physical properties	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 24.44 MPa, min. After Aging 27.21 MPa, min. Elongation: Before Aging 513%, min. After Aging 541%, min.
Freedom from holes	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, 80 of 80 passed of each size
Residual Powder	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass average 0.84 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 Medical Examination Gloves (Nitrile) are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K171422.