January 19, 2023

Yangzhou Saraguard Medical Supplies Co.,Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K223250
Trade/Device Name: Disposable Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 20, 2022
Received: December 20, 2022

Dear Boyle 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
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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)*
K223250

Device Name
Disposable Nitrile Examination Glove

Indications for Use *(Describe)*
The disposable nitrile medical examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger 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

K223250

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

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Date of Preparation: Oct.21,2022

Designated Submission Correspondent

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2.0 Device Information

Trade name: Disposable Nitrile Examination Glove
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): XS,S, M, L, XL

3.0 Classification

Production code: LZA
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Predicate Device#:
Manufacturer: Ever Global (Vietnam) Enterprise Corp
Device: Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color

510(k) number: K171422

Reference Device#:
Manufacturer: GUANG DONG KINGFA SCI. & TECH.CO., LTD.
Device: Nitrile examination gloves
510(k) number: K203593

5.0 Indication for Use

The disposable nitrile medical examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

6.0 Device Description

The subject device is powder free nitrile examination gloves. The subject device is available in color blue and white, and it provides five specifications: XS,S,M,L and XL. The subject device is non-sterile.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device	Predicate Device	Reference Device	Remark
Product Code	LZA	LZA	LZA	Same
510(k) Reference	K223250	K171422	K203593	----
Regulation No.	21CFR880.6250	21CFR880.6250	21CFR880.6250	Same
Class	I	I	I	Same
Intended Use/Indication for Use	The disposable nitrile medical examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	The Nitrile powder free patient examination Glove, is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	The nitrile examination glove is intended to be worn on the hands of examiners to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.	Same
Powdered or Powered free	Powdered free	Powdered free	Powdered free	Same
Device material composition	Nitrile	Nitrile	Nitrile	Same
Gloves sizes	XS,S,M,L,XL	XS,S,M,L,XL	S,M,L,XL	Same
If gloves are single use	Yes	Yes	Yes	Same
Design Feature	Ambidextrous	Ambidextrous	Ambidextrous	Same
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Color	Blue/White	White/ Blue/ Black/ Pink	Blue	Similar

Dimensions - Length	Complies with ASTM D6319-19: XS/S: ≥220 mm； M/L/XL: ≥230 mm.	Complies with ASTM D6319-19: ≥230 mm.	Complies with ASTM D6319-19: S:≥220； M/L/XL: ≥230	Similar
Dimensions - Width	Complies with ASTM D6319-19: XS: 70±10mm; S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm;	Complies with ASTM D6319-19: XS: 75±5mm; S:85±5mm; M:95±5mm; L: 105±5mm; XL: 115±5mm;	Complies with ASTM D6319-19: S: 80±10mm; M: 95±10mm; L: 110±10mm; XL: 120±10mm	Similar
Dimensions - Thickness	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Same
Physical Properties - Tensile Strength	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Same
Physical Properties - Elongation	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥400%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥400%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥400%	Same
Freedom from Holes	Complies with ASTM D6319-19 and ASTM D5151-19	Complies with ASTM D6319-19 and ASTM D5151-19	Complies with ASTM D6319-19 and ASTM D5151-19	Same

	G-1, AQL 2.5	G-1, AQL 2.5	G-1, AQL 2.5	
Powder Content	Complies with ASTM D6319-19, < 2 mg per glove	Complies with ASTM D6319-19.	Complies with ASTM D6319-19.	Same
Biocompatibility - Irritation Test	ISO 10993-23; Under the conditions of the study, not an irritant	Comply with Comply with ISO10993-10	ISO 10993-23; Under the conditions of the study, not an irritant	Same
Biocompatibility - Sensitization Test	ISO 10993-10; Under the conditions of the study, not a sensitizer	Comply with Comply with ISO10993-10	ISO 10993-10; Under the conditions of the study, not a sensitizer	Same
Biocompatibility - Acute Systemic Toxicity	ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	N/A	ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Different
Biocompatibility -Cytotoxicity	ISO 10993-5 Under conditions of the study, device extract is cytotoxic	Not Publicly Available	ISO 10993-5 Under conditions of the study, device extract is cytotoxic	Different

Analysis:

The color(blue/white) of the subject device is different with those (white/ blue/ black/ pink) of the predicate device, biocompatibility test has been performed on subject device and the test result can meet the requirements of ISO 10993 standards.

The physical dimensions are little different with that of the predicate, but they all meet the requirements of ASTM D6319. Therefore, the differences will not raise any safety and effectiveness issues.

For the Biocompatibility- Cytotoxicity and Acute Systemic Toxicity, at the neat extraction, the current device is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect, this situation is same with the reference device. So there is no effect on the substantial equivalence to the predicate device.

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Powder Free Examination Gloves, was conducted in accordance with the following standards:

ISO 10993-10:2021 *Biological Evaluation of Medical Devices - Part 10: T Part 10: Tests for skin sensitization.*

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation;

ISO 10993-5:2009 *Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity*

ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

Table 2 Biocompatibility Testing

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-23:2021 Tests For Irritation	To determine if device is a skin irritant	The device must be a non-irritant	Pass
ISO 10993-10:2021 Tests For Skin Sensitization	To determine if device is a skin sensitizer	The device must be a non- sensitizer	Pass
ISO 10993-5:2009 Tests For In Vitro Cytotoxicity	To determine if the device is potential toxicity to L-929 cells.	The device must be a non toxicity.	Cytotoxic
ISO 10993-11:2017 Tests for Acute systemic toxicity	To determine if the device will cause acute systemic toxicity in vivo	The device must be a Non- acute systemic toxicity	Pass

Performance Testing (Bench)

Physical performance qualities of the proposed device were evaluated per ASTM D6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

In summary, 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 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.*
- ASTM D6319-19, *Standard Specification for Nitrile Examination Gloves for*

Medical Application.

Table 3 Non-Clinical Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm): S:≥220; M/L/XL:≥230; Width(mm): XS: 70±10mm; S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm	Length: ＞240/Pass; Width: Blue color： XS: 74-76 /Pass S: 82-86 /Pass M: 95-97/ Pass L: 104-106/ Pass XL:115-117/ Pass White Color: XS: 73-76 /Pass S: 80-87 /Pass M: 100-103/ Pass L: 104-106/ Pass XL:114-117/ Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05	Blue color： XS: Finger:0.10-0.12/Pass Palm: 0.06-0.10/Pass S: Finger: 0.09-0.12/Pass Palm:0.07-0.09/Pass M: Finger: 0.08 -0.12/Pass Palm: 0.07-0.09/Pass L: Finger: 0.09-0.12/Pass Palm: 0.06-0.09/Pass XL: Finger: 0.11-0.12/Pass Palm: 0.06-0.09/Pass White Color: XS:

					Finger:0.09-0.10/Pass Palm: 0.07-0.10/Pass S: Finger: 0.08-0.11/Pass Palm:0.06-0.08/Pass M: Finger: 0.10-0.12/Pass Palm: 0.07-0.10/Pass L: Finger: 0.08-0.11/Pass Palm: 0.08-0.11/Pass XL: Finger: 0.08-0.11/Pass Palm: 0.07-0.09/Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			Blue color： XS: 0/125 S: 1/125 M: 0/125 L:2/125 XL: 2/125 Pass White Color: 0/125/Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			Blue color： < 2.0mg; Pass White Color: < 2.0mg; Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	Blue color： 25-30/Pass. White Color: 16-40/Pass.
			Ultimate Elongation	≥500%	Blue color： 515-580/Pass White Color: 461-577/Pass.

		After Aging	Tensile Strength	≥14MPa	Blue color： 20-30/Pass. White Color: 16-35/Pass.
			Ultimate Elongation	≥400%	Blue color： 511-565/Pass White Color: 436-521/Pass.

9.0 Discussion of Clinical and Performance Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K171422.