September 2, 2021

Zhenjiang SuHui Latex Products Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.1601, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211778
Trade/Device Name: Nitrile Examination Gloves, Green/ Blue/ Black Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: June 2, 2021
Received: June 9, 2021

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,

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)*
K211778

Device Name
Nitrile Examination Gloves,Green Color
Nitrile Examination Gloves,Blue Color
Nitrile Examination Gloves,Black Color

Indications for Use *(Describe)*
The Nitrile Examination Gloves,Green/ Blue/ Black Color are disposable devices intended for medical purposes that are 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.

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510(k) Summary

(K211778)

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

1.0 Submitter's Information

Name: Zhenjiang Suhui Latex Products Co., Ltd.
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Contact: Zhengfu Sun
Date of Preparation: 09/02/2021

Designated Submission Correspondent

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2.0 Device Information

Trade name: Nitrile Examination Gloves,Green Color
Nitrile Examination Gloves,Blue Color
Nitrile Examination Gloves,Black Color
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): Nitrile Examination Gloves, Green / Blue Color are available in XS,S,M,L,XL; Nitrile Examination Gloves, Black Color are available in 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

Manufacturer: Ever Global (Vietnam) Enterprise Corp
Device: Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color
510(k) number: K171422

5.0 Indication for Use

The Nitrile Examination Gloves,Green/Blue/Black Color are disposable devices intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.

6.0 Device Description

The subject device is powder free nitrile examination gloves. The subject device is provided in color Green, Blue or Black. The subject device is non-sterile.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	**Subject Device** (K211778)	**Predicate Device (**K171422**)**	**Remark**
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Nitrile Examination Gloves,Green/Blue/Black Color are disposable devices intended for medical purposes that are worn on the examiner's hands 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
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Labeling Information	Single-use indication, powder free, device	Single-use indication, powder	Same

	color, device name, glove size and quantity, Nitrile Glove Powder Free, Non-Sterile	free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove, Non-Sterile	

Table2 Device Dimensions Comparison

Item	Subject device (K211778)	Predicated device (K171422)	Remark
Length, mm	Blue/Green: XS/S: ⩾220 M/L/XL: ⩾230 Black: S: ⩾220 M/L/XL: ⩾230	XS/S/M/L/XL:⩾230	Similar
Width, mm	Blue/Green Color: XS:70±10; S:80±10; M:95±10; L:110±10; XL:120±10 Black Color: S:80±10; M:95±10; L:110±10; XL:120±10	XS:75±5; S:85±5; M:95±5; L:105±5; XL:115±5	Similar
Thickness, mm			
Finger	0.05	0.05	Same
Palm	0.05	0.05	Same

Analysis: The physical dimensions are little 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.

Table3 Performance Comparison

Item			Subject device (K211778)	Predicate device (K171422)	Remark
Colorant			Green/ Blue/ Black	White/ Blue/ Black/ Pink	Different
Physical	Before	Tensile	14MPa, min	14MPa, min	Same

Properties	Aging	Strength			
		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 ASTMD5151 AQL=2.5	Be free from holes when tested in accordance with ASTMD5151 AQL=2.5	Same
Powder Content			Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	Same

Analysis: The proposed device has different colors as compared to the predicate device. To address this concern, biocompatibility test has been performed on proposed device and the test result can meet the requirements of ISO 10993 standards. Therefore, the differences will not raise any safety and effectiveness issues.

Table4 Safety Comparison

Item		Subject device (K211778)	Predicate device (K171422)	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)	Under the conditions of the study, not an irritant	Comply with ISO10993-10	Same
	Sensitization (ISO 10993-10:2010 Biological	Under conditions of the study, not a sensitizer.		

	Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)			
	Cytotoxicity (ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity)	Under conditions of the study, device extract is not cytotoxic	/	Similar

8.0 Summary of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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

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.

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm): Blue/Green Color: XS/S: ≥220,M/L/XL: ≥230 Black: S: ≥220,M/L/XL: ≥230 Width(mm): Blue/Green Color: XS:70±10; S:80±10; M:95±10; L:110±10;	Length:＞230 Width: Green Color: XS:73~76; S:80~84; M:95~99；L:108~111; XL:114~117. Blue Color: XS:72~75; S:85~90; M:92~98；L:108~111;

		XL:120±10 Black Color: S:80±10; M:95±10; L:110±10; XL:120±10			XL:110~119. Black Color: S:82~90; M:93~97 ; L:108~111;XL:114~116. Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Green Color: Finger: 0.14-0.15 Palm: 0.12-0.14 Blue Color: Finger: 0.12-0.13 Palm: 0.11-0.12 Black Color: Finger: 0.15-0.16 Palm: 0.12-0.13 Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			Green:0/125 leaks Blue:0/125 leaks Black:0/125 leaks Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			Green:0.08 mg; Blue:0.07 mg; Black:0.08 mg; Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	Green:14.5-16.1 Blue:15.1-19.6 Black:14.1-41.2 Pass
			Ultimate Elongation	≥500%	Green:559-953 Blue: 745-927 Black:545-1193 Pass
		After Aging	Tensile Strength	≥14MPa	Green:14.2-15.5 Blue:14.5-15.6 Black:14.0-21.8 Pass
			Ultimate Elongation	≥400%	Green:541-805 Blue: 662-740 Black:533-797 Pass

ISO 10993-5	Cytotoxicity	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells. Pass
ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, not an irritant. Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer. Pass

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Nitrile Examination Gloves,Green/Blue/Black Color, are as safe, as effective, and performs as well as or better than the legally marketed predicated device under K171422.