



November 15, 2018

Haining Medical Products Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738, Shangcheng Rd., Pudong
Shanghai, 200120 Cn

Re: K182528

Trade/Device Name: Nitrile Glove Powder Free Black
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: September 7, 2018
Received: September 14, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182528

Device Name

Nitrile Glove Powder Free Black

Indications for Use (Describe)

The Nitrile Glove Powder Free Black is a disposable device intended for medical purposes that is 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

K182528

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: Nov.7, 2018

Designated Submission Correspondent

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China
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2.0 Device information

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

3.0 Classification

Production code: LZA
Regulation number: 21 CFR 880.6250
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 Glove Powder Free Black is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

6.0 Device description

The proposed device is Powder Free Nitrile Examination Gloves. The proposed device is black. The proposed device is non-sterile.

7.0 Technological Characteristic Comparison Table

Table 1-General Comparison

Item	Proposed device	Predicated device	Comparison
510(k) number	K182528	K171422	
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Intended Use	The Nitrile Glove Powder Free Black is a disposable device intended for medical purposes that is 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	Powdered free	Powdered free	Same

Powered free			
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder Free Black, 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 Dimensions Comparison

Predicate Device(K171422)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	75	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Proposed Device (K182528)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	75	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Comparison	SAME						

Table 3 Performance Comparison

Item			Proposed device (K182528)	Predicated device (K171422)	Comparison
Colorant			Black	White/ Blue/ Black/ Pink	Analysis 1
Physical Properties	Before Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		Ultimate	500% min	500% min	Same

		Elongation			
	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 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Same
Powder Content			0.48 mg per glove	Meet the requirements of ASTM D6124	Similar

Analysis 1: The proposed device has different color to the predicate device.

Table 4 Safety Comparison

Item		Proposed device (K182528)	Predicated 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	Under the conditions of the study, not an irritant	Same
	Sensitization (ISO 10993-10:2010 Biological Evaluation of Medical Devices -	Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	

	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, did not show potential toxicity to L-929 cells.	/	Similar

8.0 Discussion of non-clinical and clinical test performed

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 D5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.

D6319-10 (Reapproved 2015), Standard Specification For Nitrile Examination Gloves For Medical Application.

Clinical testing is not needed for this device.

9.0 Conclusion

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