



March 30, 2021

Great Harvest Trading Co., Ltd.  
% Boyle Wang  
Official Correspondent  
Shanghai Truthful Information Technology Co., Ltd.  
RM.608, No.738, Shangcheng Rd., Pudong  
Shanghai, Shanghai 200120  
China

Re: K210058

Trade/Device Name: Blue Nitrile Exam Glove, Powder Free  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Non-Powdered Patient Examination Glove  
Regulatory Class: Class I, reserved  
Product Code: LZA  
Dated: March 16, 2021  
Received: March 22, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jiangsong Jiang -S**  
**(Affiliate)**

For Ryan Ortega, Ph D.  
Acting 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



# 510(k) Summary

## K210058

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

### **1.0 Submitter's Information**

Name: Great Harvest Trading Co., Ltd.  
Address: Xinghe Road, Dongying City 257100, Shandong, China  
Phone Number: +86-13508943885  
Contact: Chongfeng Zhao  
Date of Preparation: Mar.16,2021

### **Designated Submission Correspondent**

Mr. Boyle Wang  
Shanghai Truthful Information Technology Co., Ltd.  
Room 608, No. 738 Shangcheng Rd., Pudong, Shanghai 200120, China  
Tel: +86-21-50313932  
Email: Info@truthful.com.cn

### **2.0 Device Information**

Trade name: Blue Nitrile Exam Glove, Powder Free  
Common name: Patient Examination Gloves  
Classification name: Non-powdered patient examination glove  
Model(s): 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 Blue Nitrile Exam Glove, Powder Free 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 blue. The subject device is non-sterile.

## 7.0 Technological Characteristic Comparison Table

**Table1-General Comparison**

<b>Item</b>	<b>Subject Device (K210058)</b>	<b>Predicated Device (K171422)</b>	<b>Remark</b>
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Blue Nitrile Exam Glove, Powder Free 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 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 color, device name, glove size and quantity, Nitrile Glove Powder Free Blue,	Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove,	Same

	Non-Sterile	Non-Sterile	
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**Table2 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
Subject Device (K210058)	Designation	Size				Tolerance	
		S	M	L	XL		
	Length, mm	230	230	230	230	±10	
	Width, mm	80	95	110	120	±10	
	Thickness, mm:						
	Finger	0.08					±0.03
Palm	0.08					±0.03	
Remark	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.

**Table3 Performance Comparison**

Item			Subject device (K210058)	Predicated device (K171422)	Remark
Colorant			Blue	White/ Blue/ Black/ Pink	Same
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	Be free from holes when tested in accordance with	Same

	ASTMD5151 AQL=2.5	ASTMD5151 AQL=2.5	
Powder Content	0.05 mg per glove	Meet the requirements of ASTM D6124	Same

**Table4 Safety Comparison**

Item	Subject device (K210058)	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)	Comply with ISO10993-10	Same
	Sensitization (ISO 10993-10:2010 Biological 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)	/	Similar

## **8.0 Discussion of Non-clinical and Performance 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.

## **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 Blue Nitrile Exam Glove, Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicated device Disposable Powder Free Nitrile Examination Glove cleared under K171422.