



Food and Drug Administration
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July 14, 2016

Zibo Flourish Trading Co., Ltd.
% Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
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Beijing, 101121 CHINA

Re: K161072

Trade/Device Name: Powder Free Grey Vinyl Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: June 24, 2016
Received: June 27, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

Indications for Use

510(k) Number (if known)

K161072

Device Name

Powder Free Grey Vinyl Examination Gloves

Indications for Use (Describe)

The Powder Free Grey Vinyl Patient Examination Gloves is a 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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Tab #2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K161072

1. Date of Preparation: 2016-6-24

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Powder Free Grey Vinyl Examination Gloves
Device Name: Vinyl Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Classification: I
Product Code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Intended Use Statement:

The Powder Free Grey Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K150224

Product Name: Blue Vinyl Examination Gloves Powder free

Manufacturer: Zibo Sanying Trade Co., Ltd.

6. Device Description

The proposed device, Powder Free Grey Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

The proposed is Powder Free Grey Vinyl Patient Examination Gloves, and includes variations of different size.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D5250-06, Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.

ASTM D 5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.

ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.

ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent Comparison Conclusion

Table III-1 General Comparison

ITEM	Proposed Device Powder Free Grey Vinyl Patient Examination Gloves	Predicate Device (k150224) BLUE VINYL GLOVES POWDER FREE	Remark
Product Code	LYZ	LYZ	SE
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SE
Class	I	I	SE
Intended Use	The Powder Free Grey Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	The BLUE VINYL GLOVES POWDER FREE is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	SE
Powdered or Powdered free	Powdered free	Powdered free	SE

Table III-3 Device Dimensions Comparison

Proposed Device	Designation	Size						Tolerance
		XS	S	M	L	XL	XXL	
Powder Free Grey Vinyl Patient Examination Gloves	Length, mm	≥230	≥230	≥230	≥230	≥230	≥230	min
	Width, mm	75	85	95	105	115	125	±5
	Thickness, mm:							
	Finger	≥0.05						min
	Palm	≥0.08						min
	Cuff	≥0.06						min
Predicate Device (k150224)	Designation	Size				Tolerance		
		S	M	L	XL			
BLUE VINYL GLOVES POWDER FREE	Length, mm	≥240	≥240	≥240	≥240	min		
	Width, mm	85	95	105	115	±5		
	Thickness, mm:							
	Finger	≥0.10						min
	Palm	≥0.08						min
	Cuff	≥0.06						min
Remark	Complies with ASTM D5250							

Table III-3 Performance Comparison

ITEM			Proposed Device Powder Free Grey Vinyl Patient Examination Gloves	Predicate Device (k150224) BLUE VINYL GLOVES POWDER FREE	Remark
Colorant			Grey	Blue	Complies with ASTM D5250
Physical Properties	Before Aging	Tensile Strength	≥12 MPa, min	≥13 MPa, min	Complies with ASTM D5250
		Ultimate Elongation	≥300 % min	≥400 % min	
	After Aging	Tensile Strength	≥12 MPa, min	≥13 MPa, min	
		Ultimate Elongation	≥300 % min	≥400 % min	
	Comply with ASTM D5250			Comply with ASTM D5250	SE
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	SE
Powder Content			1.8 mg per glove	Meet the requirements of ASTM 5250	SE

Table III-4 Safety Comparison

ITEM		Proposed Device Powder Free Grey Vinyl Patient Examination Gloves	Predicate Device (k150224) BLUE VINYL GLOVES POWDER FREE	Remark
Material		Vinyl	Vinyl	SE
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
	Sensitization	Under conditions of the study, not a sensitizer.		
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	SE

Conclusion

The Zibo Flourish Tading Co., LTD Powder Free Grey Vinyl Patient Examination Glove is substantially equivalent to the predicate device, Zibo Sanying Trade Co., LTD. Blue Vinyl Examination Gloves Powder Free. Based on the non-clinical tests performed, the subject device is as safe, as effective and performs as well as the legally marketed predicate device, cleared under K150224.

The proposed device, Powder Free Grey Vinyl Patient Examination Gloves, is determined to be Substantially Equivalent (SE) to the predicate device in respect of safety and effectiveness.