DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 11, 2017

Shandong Zhi Hong Medical Products, Co. Ltd.
% Melo Zhang
Official Correspondent
Intco Medical Industries, INC.
805 Barrington Ave
Ontario, California 91764

Re: K171317
Trade/Device Name: Clear Vinyl Powder-free Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: August 21, 2017
Received: August 23, 2017

Dear Melo Zhang:

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S
2017.09.11 19:39:48 -04'00'

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171737

Device Name
Clear Vinyl Powder-free Patient Examination Gloves

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand 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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Shandong Zhi Hong Medical Products, Co. Ltd.
231 Dongqi Industrial Park
Qingzhou City, Shandong
China

510(K) SUMMARY

Submitter / 510(k) Sponsor

Shandong Zhi Hong Medical Products, Co. Ltd.
231 Dongqi Industrial Park
Qingzhou City, Shandong
China

Contact Person

Melo Zhang
Official Correspondent
Phone: 909 980 1678
Email: melozhang@intcous.com

Summary Preparation Date

Sept 5, 2017

Type of 510(k) Submission

Traditional

Device Name / Classification

Name of Device: Clear Vinyl Powder-free Patient Examination Gloves
Proprietary Name: Powder-Free Vinyl Patient Examination Gloves
Common Name: Vinyl Patient Examination Glove
Classification Name: Patient Examination Glove
Product Code: LYZ
Product Class: Class I
Regulation #: 21 CFR 880.6250
Classification Panel: General Hospital

Predicate Device

Powder-free PVC Vinyl Exam Gloves, Hebei Grandeast Plastic Products Co., Ltd.
K142703

Shandong Zhi Hong Medical Products, Co. Ltd.
231 Dongqi Industrial Park
Qingzhou City, Shandong
China

Device Description

The proposed devices, Powder-free Vinyl Exam Gloves are non-sterile, clear, non-colored and disposable medical gloves intended to be worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Non Clinical Performance Tests

Scientific concepts: The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, to prevent contamination between patient and examiner; Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

Significant physical and performance characteristics of the device: glove production is based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

Subject Clear Vinyl Powder-free Patient Examination Gloves do not contain any USP powder per the results of testing conducted on the gloves. The residual powder testing is conducted per standards of ASTM D-6124-06, which demonstrates that the powder free glove is less than 2mg/pc. Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Glove, 80LYZ, and meets all requirement of ASTM Standard D5250-06.

Overall Length: 230mm min
Width: 94mm min
Palm Thickness: 0.09 mm min
Fingertip Thickness: 0.086 mm min
Tensile Strength (Mpa)
Before aging 15Mpa min
After aging 13Mpa min
Ultimate Elongations
Before aging 495% min
After aging 415% min

Indications for Use

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

Shandong Zhi Hong Medical Products, Co. Ltd.
231 Dongqi Industrial Park
Qingzhou City, Shandong
China

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristics	Proposed Device	Predict Device (K142703)	Comparison Conclusion
Product Name	Shandong Zhi Hong Medical Products, Co. Ltd. Clear Vinyl Powder-free Patient Examination Gloves,	Hebei Grandeast Plastic Products Co., Ltd. Glide-On Vinyl Examination Gloves	
Product Code	LYZ	LYZ	Similar
Intended Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Similar
Length on Large Size	Average over 232.23mm	Average over 230mm	Similar
Width of Palm on Large Size	Average 95mm	Average 95mm	Similar
Palm Thickness	Average 0.095 mm	Average 0.095 mm	Similar
Fingertip Thickness	Average 0.09 mm	Average 0.09 mm	Similar
Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Similar
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces	Similar

	two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	gloves out of 125 pieces gloves. AQL 2.5 is met.	
Biocompatibility Result: Primary Skin Irritation	Under the conditions of the study, the subject device is not an irritant	Under the conditions of the study, the subject device is not an irritant	Similar
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.96 Average Ultimate Elongations: 519%	Average Tensile Strength (Mpa): 16.96 Average Ultimate Elongations: 519%	Similar
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.92 Average Ultimate Elongations: 480%	Average Tensile Strength (Mpa): 14.92 Average Ultimate Elongations: 480%	Similar
Dermal Sensitization	Under the conditions of the study, the subject device is not an sensitizer	Under the conditions of the study, the subject device is not an sensitizer	Similar
Summary	Shandong Zhi Hong Medical Products, Co. Ltd. Clear Vinyl Powder-free Patient Examination Gloves are Similar to the predicate, K142703. Both gloves have the same intended use, same material and the same device performance.		

Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the subject device is as safe, as effective, and performs as well as the predict device.