March 9, 2018

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

Re: K173078
Trade/Device Name: Powder-free Clear Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: January 29, 2018
Received: February 2, 2018

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.

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.

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,

Michael J. Ryan -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

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)*

K173078

Device Name

Powder-free Clear Vinyl Patient Examination Gloves

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) SUMMARY K173078

1. Submitter's Identification:

Yongsheng Medical Products Co., Ltd
No. 4519 Qingzhou Road
Shao De Industrial Park
China
Contact Person:
Melo Zhang
Official Correspondent

Date summary prepared: March 6, 2018

2. Name of the Device:

Yongsheng Medical Products Co., Ltd
Powder-free Clear Vinyl Patient Examination Gloves

3. Trade Name

Yongsheng Medical Products Co., Ltd
Powder-free Clear Vinyl Patient Examination Gloves

4. Predicate Device Information:

Powder-free PVC Vinyl Exam Gloves
Hebei Grandeast Plastic Products Co., Ltd.
K l42703

5. Device Description:

A Powder-free Clear Vinyl Patient Examination Gloves 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). Our Powder-free Clear Vinyl Patient Examination Gloves do not contain any UPS powder according to 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, LYZ, and meets all requirement of ASTM Standard 5250-06.

6. Indication 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.

7. Technological Characteristic Comparison:

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

Device Characteristics	Proposed Device	Predict Device (K142703)	Comparison Conclusion
Product Name	Yongsheng Medical Products Co., Ltd Powder-free Clear Vinyl 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	>230 mm	Similar
Width of Palm on Large Size	Average 95mm	>105 mm	Similar
Palm Thickness	Average 0.095 mm	0.10 mm	Similar
Fingertip Thickness	Average 0.09 mm	0.10 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.	< 2 mg per glove	Similar
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 gloves. AQL 2.5 is met.	Comply with ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 200 gloves. AQL 2.5 is met.	Similar

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): 17.4 Average Ultimate Elongations: 519%	Average Tensile Strength (Mpa): 11 Average Ultimate Elongation: >300%	Similar
After Aging: Tensile Strength (Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.96 Average Ultimate Elongations:480.76%	Average Tensile Strength (Mpa): 11 Average Ultimate Elongation >300%	Similar
Dermal Sensitization	Under the conditions of the study, the subject device is not a sensitizer	Under the conditions of the study, the subject device is not a sensitizer	Similar
Summary	Yongsheng Medical Products Co., Ltd Powder-free Clear Vinyl Patient Examination Gloves are similar to the predicate, K142703.		

8. Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:

The standards used for Yongsheng Medical Products Co., Ltd glove production is based on ASTM-D5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements, Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

Our gloves meet our "powder-free" claims and contain no more than 2 mg powder per glove.

9. Conclusions:

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.