June 20, 2019

Anhui Intco Medical Products Co. Ltd
% Derek Tian
Official Correspondent
Intco Medical Industries, Inc.
805 Barrington Ave
Ontario, California 91764

Re: K190095
Trade/Device Name: Powder-Free Clear Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: March 21, 2019
Received: March 26, 2019

Dear Derek Tian:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
THT4B2: Disinfection, Reprocessing and Personal Protection
Acting Assistant Director, THT4B1: Sterility Devices
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190095

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 examiners' hands or fingers to prevent contamination between patients and examiners

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.

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

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Anhui Intco Medical Products Co,ltd
No.1 Haitang Road, Suixi District economic development area,
Huaibei City, Anhui Province

510(k) SUMMARY

K190095

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

Date summary prepared: June 19, 2019

1. **Submitter's Identification:**
   Anhui Intco Medical Products Co, Ltd.
   No.1 Haitang Road, Suixi District economic development area
   Huaibei City, Anhui Province
   China

   Contact Person
   Jacken Cai
   Product Manager
   Tel: 86-13853653818
   Email: jackencai@intco.com

   US Representative Contact Person
   Dongqi Tian
   Tel: 909-980-1678
   Email: Tian.Dongqi@hotmail.com

2. **Name of the Device:**
   Powder-free Clear Vinyl Patient Examination Gloves

3. **Common Name:**
   Patient Examination Gloves

4. **Regulation number: 21 CFR 880.6250**

5. **Class: I**

6. **Product Code: LYZ**

7. **Predicate Device Information:**

Device name: Vinyl Examination Gloves, Powder-Free, Clear
510(k) #: K022091
Manufacturer name: Tangshan Zhonghong Pulin Food Products Co., Ltd

8. **Device Description:**
The Vinyl Examination Gloves are single use only, disposable gloves intended for medical purposes to be worn on the hands or fingers of examiners. The gloves are powder-free, clear and are made of poly vinyl chloride. The gloves are offered non-sterile and are available in small, medium, large and extra-large sizes.

9. **Indication for Use:**
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 patients and examiners.

10. **Technological Characteristics**

Side by side comparison (including technological characteristics) between subject and predicate device

		Proposed Device (K190095)	**Predicate Device (K022091)**	**Comparison Conclusions**
Device Name		Powder-free Clear Vinyl Patient Examination Gloves	Vinyl Examination Gloves, Powder-Free, Clear	Similar
Manufacturer		Anhui Intco Medical Products Co, ltd.	Tangshan Zhonghong Pulin Food Products Co., Ltd.	Different
Indication for use		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 patients and examiners.	A Vinyl patient examination glove is a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Labeling: Labels on the carton		Face: Proprietary name, common name, contents size, lot number, distributed by Side: Proprietary name, Indications for Use contents, size, lot number, distributed by, country and instruction for storage" Store in a cool and dry place. Avoid Direct sunlight	N/A	Different

Labels on the dispenser glove		Face: Powder-free Clear Vinyl Patient Examination Gloves, non-sterile, single use only, contents: 100 gloves (by weight) size, manufactured for: Intco Medical Industries, Inc. or other importers . Side: Powder-free Clear Vinyl Patient Examination Gloves, non-sterile, single use only Contents: 100 gloves (by weight), size, lot number, distributed by: Manufactured for:	Face: Vinyl examination Glove Powder-free, Contents: 100 gloves (by weight) Size: < Distributed by: Baldur systems Corp. Hayward, CA 94545 Side: Vinyl Examination Glove Powder-free/Single Use/Non-sterile, Content: 100 gloves (by weight) Size, made in China, Lot number	Similar
Device Materials		Poly Vinyl Chloride	Poly Vinyl Chloride	Similar
Color		Clear	Clear	Same
Technological Characteristics as per ASTM 5250-06 (Reapproved 2011) (FDA recognition #: 6-183) Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Applications	Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 17.44 Average Ultimate Elongations: 519.4%	Average Tensile Strength (Mpa): 17.00 Average Ultimate Elongations: 500%	Similar
	After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 15 Average Ultimate Elongations: 481.96%	Average Tensile Strength (Mpa): 15 Average Ultimate Elongations: 450%	Similar
	Available Sizes	S, M, L, XL	S, M, L, XL	Same
	Overall Length on Medium Size	Average over 232.23mm	Average over 232.23mm	Same
	Width of Palm on Medium Size	Average 95.08mm	Average 95.08mm	Same
	Palm Thickness	Average 0.095 mm	Average 0.095 mm	Same
	Finger Thickness	Average 0.090 mm	Average 0.090 mm	Same
Residual Powder ASTM D6124-06 of residual or powder on finished powder-free gloves as < 2 mg per glove.		Meets ASTM D6124-06 Residual powder on finished powder-free gloves was < 2 mg per glove	Meets ASTM D6124-06 Residual powder on finished powder-free gloves was < 2 mg per glove	Same
Pinhole /Water Leak Test According to ASTM D5151-06, (Reapproved 2011) Sample 4, AQL 2.5		Meets ASTM D5151-06 According to ASTM D5151-06. Testing result indicated pinhole were found in two gloves out of 125 gloves examined. AQL 2.5 . Criteria was met	Meets ASTM D5151-06 According to ASTM D5151-06. Testing result indicated pinhole were found two gloves out of 125 gloves. AQL 2.5 was met.	Same

-Biocompatibility	Primary Skin Irritation ISO 10993-10:2010 ISO Skin Irritation Study	Under the conditions of the study, the test material was not an irritant in the white rabbit model.	Under the conditions of the study, the test material was not an irritant in the white rabbit model.	Same
	Dermal Sensitization ISO 10993-10:2010 ISO Skin Dermal Sensitization	Under the conditions of the study, an extract of this test material was not a sensitizer in the Guinea pig model.	Under the conditions of the study, an extract of this test material was not a sensitizer in the Guinea pig model.	Same
	Cytotoxicity ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Test For In Vitro Cytotoxicity. Acceptance criteria : Cells treated with neat extract from tested article are not lysed	Under conditions of the study, the device extract is not cytotoxic to the mammalian cell culture (mouse fibroblasts L929 cells)	N/A	Different

11. **Summary of Non-Clinical Performance Data**

The subject device was tested using the methodologies recommended in the following standards and the results met the acceptance criteria in the standards:

i) ASTM 5250-06 (Reapproved 2011) (FDA recognition # 6-183) Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Applications
Acceptance Criteria:
Length: ≥ 230 mm (min)
Width (size Medium): 90-100 mm
Thickness Finger 0.05 mm (min)
Thickness Palm 0.08 mm (min)
The subject device testing results meets all acceptance criteria.

ii) ASTM D5151-06 (FDA recognition #: 6-175) Standard Test for Detection of Holes in Medical Gloves
Standard acceptance criteria:
Results: Meets ASTM D5151-06
Sampling -4 AQL 2.5 of 125 gloves tested, 2 gloves were found to leak.

iii) ASTM D6124-06 (FDA recognition #: 6-178) Standard Test Method to Determine the Amount of Residual Powder and Non-powder Solids on Medical Gloves.
Standard acceptance criteria: Powder residue < 2 g per glove
Results: Meets ASTM D6124-06. We found that our gloves had 2 mg/glove of residual powder.

iv) ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: test for Irritation and Skin sensitization.Standard acceptance criteria: No skin irritation in the white rabbit model and no skin sensitization in the guinea pig model.
Results: Meets ISO 10993-10:2010
Skin Irritation: Under the condition of the test, the device extracts were not an irritant.
Skin Sensitization: Under the condition of the test, the device extracts were not a sensitizer.

v) ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Test for *in vitro* Cytotoxicity
Standard acceptance criteria: The percent of cytotoxicity should not be greater than 30% when cells are exposed to neat test article extract.
Results: Under the condition of the test, the neat extracts was not cytotoxicity

12. **Summary of Clinical Performance Data**
    NA

13. **Conclusion:**
    The conclusions drawn from the nonclinical tests demonstrate that the subject device (K190095) is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K022091).