July 22, 2019

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

Re: K191092
Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves, Yellow Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: April 16, 2019
Received: April 24, 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.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*

K191092

Device Name

Powder-free vinyl patient examination gloves, Yellow Color

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.

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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

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

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

   Contact Person
   Jacken Cai
   Tel: 86-13853653818

   Date summary prepared: July 17, 2019

2. **Name of the Device:**
   Powder-free Vinyl Patient Examination Gloves, Yellow Color

3. **Common Name:**
   Non-powdered patient examination glove

4. **Predicate Device Information:**
   Device name: Vinyl Examination Gloves, Powder-Free, Yellow
   510(K) #: K022091
   Manufacturer name: Tangshan Zhonghong Pulin Food Products Co., Ltd

5. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Gloves, 80 LZA, and meets all requirements of ASTM standard D-6139 and ASTM D-5250.

6. **Intended Use:**

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.

7. **Technological Characteristics**

	Subject Device (K191092)	**Predicate Device** (K022091)	**Comparison**
Description	Powder-free Vinyl Patient Examination Gloves, Yellow Color by Anhui Intco Medical Products Co, ltd.	Vinyl Examination Gloves, Powder-Free, Yellow by Tangshan Zhonghong Pulin Food Products Co., Ltd.	Similar
Indication for use	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.	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.	Same
Labeling: Labels on the carton	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor **name,** and manufacturer address.	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor **name,** and manufacturer address.	Same
Device Materials	Poly Vinyl Chloride	Poly Vinyl Chloride	Same
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: 475%	Similar
Overall Length on Medium Size	Average over 232.23mm	Average over 230.00 mm	Similar

Width of Palm on Medium Size	Average 95.08mm	Average 95.00mm	Same
Palm Thickness	Average 0.095 mm	Average 0.095 mm	Same

Figure Thickness	Average 0.090 mm	Average 0.090 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.	Same
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Same
Biocompatibility			
Primary Skin Irritation	Based on the conditions of the test the animal model did not demonstrate an irritation response from both device extract. Therefore, the device is not an irritant	Based on the conditions of the test the animal model did not demonstrate an irritation response from both device extract. Therefore, the device is not an irritant	Same
Dermal Sensitization	Based on the conditions of the test the animal model did not demonstrate a sensitization response from both device extract. Therefore, the device is not a sensitizer	Based on the conditions of the test the animal model did not demonstrate a sensitization response from both device extract. Therefore, the device is not a sensitizer	Same

Cytotoxicity	Based on the conditions of the test assay did not demonstrate any significant cell lysis from the device extract. Therefore, the device is not cytotoxic	/	

8. Summary of Non-Clinical Testing:

The standards used for Anhui Intco Medical Products Co, ltd.'s gloves product are based on ASTM D-6319 and ASTM D-5250. All testing meets requirements for physical and dimensions testing conducted on gloves. Inspection level S-2, AQL 2.5.

The FDA 1000 ml Water Fill Test based on ASTM-D5151-06 was also conducted samplings of AQL 2.5 inspection level G-1, meeting these requirements. Primary Skin Irritation and Skin Sensitization testing was conducted with results showing no primary skin irritant or sensitization reactions.

A Residual Powder Test that based on ASTM D-6124 for start to finish inspection is conducted to ensure that our gloves meet our "powder-free" claims (contains no more than 2 mg powder per glove).

9. Summary of Clinical Tests Performed:

Not Applicable

10. Conclusions:

Based on the Indication for Use, technological characteristics, and non-clinical performance data, Powder-free Vinyl Patient Examination Gloves, Yellow Color (K191092, 510(K) number) is as safe, as effective, and perform as well as or better than the legally marketed predicate devices, Vinyl Examination Gloves, Powder-Free, Yellow (K022091)