April 8, 2022

Shandong Intco Medical Products Co, Ltd.
% John Zhao
Official Correspondent
Intco Medical Industries, Inc.
805 Barrington Ave.
Ontario, California 91764

Re: K213509
Trade/Device Name: Latex Examination Gloves, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: March 8, 2022
Received: March 9, 2022

Dear John Zhao:

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,

Clarence W. Murray, III, PhD
Assistant Director
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)*
K213509

Device Name
Powder Free Latex Examination Glove

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 Intco Medical Products Co., Ltd.
9888 Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, 262500

510(K) SUMMARY

1. **Submitter's Identification:**

Shandong Intco Medical Products Co, ltd.
9888 Qiwang Road, Naoshan Industrial Park,
Qingzhou, Shandong, 262500
China

Contact Person:
Haisheng Yu
Vice General Manager

Date summary prepared: Oct. 28, 2021

2. **Product Trade Name:**
Shandong Intco Medical Products Co., Ltd
Latex Examination Gloves, Powder Free

3. **Device Classification Name:**
Patient Examination gloves (21 CFR 880.6250)

4. **Device Class:**
Class I.

5. **Product Code:**
LYY

6. **Predicate Devices:**
K161833 – *Careglove Global SDN BHD*

7. **Reason for 510(k) Submission:**
New device.

8. **Device Description:**
Powder Free Latex Examination Gloves meets all the current specifications listed under the ASTM Specification D3578-05, Standard Specification for Rubber Examination Gloves. The principal operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the counter single use.

9. **Intended Use:**

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

10. **Technology Characteristic Comparison between the device and predicate device:**

There is no difference in technology characteristic compared to the predicate device. Gloves are made from natural rubber latex compound. Non-Sterile, Powder Free Latex Examination Gloves has the below technological characteristic compared to ASTM or Equivalent standards.

Characteristics and Parameters	**Powder Free Latex Examination Glove**	**Powder Free Latex Examination Glove (K161833)**	**Comparison**
Product Code	LYY	LYY	Same
Intended Use	*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*	*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*	Same
Classification	Class I	Class I	Same
Raw Rubber Material	Natural Rubber Latex	Natural RubberLatex	Same
Color	No color pigment added. Natural White	No color pigment added.Natural White	Similar
Overall Length Minimum230mm	Average: 247 mm	Meet ASTM D3578-05	Similar

Width S: 75mm – 95mm; M: 85mm – 105mm; L:100mm– 120mm	Average: S: 85mm M:96 mm L:104 mm:	S: 82mm – 87 mm M: 94mm – 97mm L: 102mm – 107mm	Similar
Palm Thickness (Minimum 0.08mm)	Average: 0.122 mm	0.12mm - 0.14 mm	Similar
Finger Thickness (Minimum 0.08mm)	Average:0.156 mm	0.10 - 0.13 mm	Similar
Tensile Strength (before age) Minimum 18 MPa	Average: 26.17MPa	21.18 – 26.17 MPa	Similar
Tensile Strength (After Age) Minimum 14 MPa	Average: 24.82MPa	18.28 – 23.88 MPa	Similar
Stress at 500% Elongation 5.5 MPa Maximum	4.99 MPa	3.0 – 4.2 MPa	Similar
Ultimate Elongation before age (Minimum 500%)	Average: 759.85%	750.20% – 820.20%	Similar
Ultimate Elongation after age (Minimum 400%)	Average: 678.62%	550.40% - 700.50%	Similar
Freedom of Holes Meet AQL 2.5 at G1	Meet AQL 2.5 with G1	Meet AQL 2.5 with G1.	Similar
Residual powder test (Less than 2mg/glove)	Average powder residue for each size: S: 0.43 mg/glove; M 0.31 mg/glove; L 0.47 mg/glove	Contained less than 2 mg/glove	Similar

Protein Testing	S size: Less than 50 µg/dm2; M size: Less than 50 µg/dm2; L size: Less than 50 µg/dm2	less than 50 µg/dm2	Similar
Primary Skin Irritation	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Same
Dermal Sensitization	Under the conditions of study, not a sensitizer.	Under the conditions of study, not a sensitizer.	Same
Acute Systemic Toxicity	Under the conditions of the study, no evidence of systemic toxicity from the extract	Not available	Different

11. Non-clinical Testing Summary:

Provided below is a summary of the standards and the test methodology that the subject device met the specification and acceptance criteria of the subject device.

Test Methodology	Purpose	Acceptance Criteria	Result
Biological Evaluation of Medical Devices - Part 10	Tests For Irritation And Skin Sensitization.	ISO 10993-10:2010	Complied with the standard
ASTM D6124-06 (Reapproved 2017)	Standard Test Method for Residual Powder on Medical Gloves	ASTM D6124-06	Complied with the standard
ASTM D5151-06(Reapproved2015)	Standard Test Method for Detection of Holes in Medical Gloves.	ASTM D5151-06	Complied with the standard
ASTM D3578 − 19	Standard Specification for Rubber Examination Gloves	ASTM D3578 − 19	Complied with the standard

12. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that Shandong Intco Medical Products Co., Ltd. Powder Free, Latex Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device.