August 24, 2023

Shandong YINGHONG Medical Products Co., Ltd.
℅ Jason Ji
Official Correspondent
Intco Medical Industries, Inc
805 Barrington Ave.
Ontario, California 91764

Re: K222103
Trade/Device Name: Nitrile Patient Examination Gloves, Powder Free, Pink Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 11, 2022
Received: July 21, 2023

Dear Jason Ji:

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222103

Device Name
Nitrile Patient Examination Gloves, Powder Free, Pink Color

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Shandong YINGHONG Medical Products Co., Ltd.

No.15 East Road, Hongrun Industry Park, Qingzhou, Shandong, China

510(K) SUMMARY
K222103

1. **Submitter's Identification:**

Shandong YINGHONG Medical Products Co.,
Ltd No.15 East Road, Hongrun Industry Park,
Qingzhou, Shandong,
China

Contact Person:
Emily Dong
Tel: +86-5366136888

Submission Correspondent
Company: Intco Medical Industries, Inc
805 Barrington Ave
Ontario, CA 91764
Primary Contact Name: Jason Ji
Tel: 1-909-980-1678 (Ext: 113)
Email: jasonji@intcous.com
Secondary Contact: John Zhao
Tel: 1-909-980-1678 (Ext:112)
Email: johnzhao@basicmedical.com

Date summary prepared:
August 10, 2023

2. **Product Trade Name:**
Nitrile Patient Examination Gloves, Powder Free, Pink Color

3. **Device Classification Name:**
Non-Powdered Patient Examination Gloves

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

5. **Device Class:**
Class I.

6. **Product Code:**
LZA.

7. **Predicate Devices:**
K190942 – Ever Growth (Vietnam) Co., Ltd.

8. Device Description:

The subject device in this 510(k) Notification is Nitrile Patient Examination Gloves, Powder Free, Pink Color. The subject device is a patient examination glove made from nitrile compound, pink color, powder free and non-sterile (Per 21 CFR 880.6250, class I).

These gloves are pink in color and are powder free. The gloves are ambidextrous single use disposable devices that come in six sizes (XS, S, M, L, XL and XXL).

9. Indications 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 patient and examiner.

10. Technological Characteristics Comparison Table:

Characteristics and Parameters	Shandong YINGHONG Medical Products Co., Ltd. Nitrile Patient Examination Gloves, Powder Free, Pink Color	Ever Growth (Vietnam) Co. , Ltd. Disposable Powder Free Nitrile Examination Glove, Pink Color	Comparison Analysis
K-Number	K222103 (Subject Device)	K190942 (Predicate)	-
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Intended 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.	The Nitrile Powder Free patient examination glove is a non- sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	Same
Material	Nitrile	Nitrile	Same
Color	Pink	Pink	Same
Single Use	Yes	Yes	Same
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Powdered or Powder Free	Powder Free	Powder Free	Same
	Complies with ASTM D6319-19 Overall Length (mm) For XS, S, Min 220mm For M, L, XL, XXL Min 230mm	Complies with ASTM D6319-10 Overall Length (mm) For XS, S, Min 220mm For M, L, XL Min 230mm	

Dimensions ASTM D6319-19	Complies with ASTM D6319-19 X-Small 70±10mm Small 80±10mm Medium 95±10mm Large 110 ±10mm X Large 120±10mm XX Large 130 ±10mm	Complies with ASTM D6319-10 X-Small 70±10mm Small 80 ±10mm Medium 95±10mm Large 110 ±10mm X Large 120 ±10mm XX Large N/A	[1.] Different
	Thickness Palm - 0.05mm min. Finger - 0.05 mm min.	Thickness Palm - 0.05mm min. Finger - 0.05 mm min.	Same
Physical properties ASTM D6319-19	Meets ASTM D6319-19 Tensile Strength: Before Aging 14 MPa, min. After Aging 14 MPa, min. Elongation: Before Aging 500% min. After Aging 400% min.	Meets ASTM D6319-10 Tensile Strength: Before Aging 14 MPa, min. After Aging 14 MPa, min. Elongation: Before Aging 500% min. After Aging 400% min.	Similar
Freedom from pinholes ASTM D6319-19 ASTM D5151-19	In accordance with ASTM D6319-19 and ASTM D5151- 19, G-1, AQL 2.5	In accordance with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 2.5	Similar
Residual power test ASTM D6124-06	Three Lot, Average power residue ＜2mg per glove	Average powder residue ＜ 2mg per glove	Same
Skin Irritation Test ISO 10993-10	Passed. Under the conditions of study, not an irritant.	Passed. Under the conditions of study, not an irritant.	Same
Skin Sensitization Test ISO 10993-10	Passed. Under the conditions of study, not a sensitizer	Passed. Under the conditions of study, not a sensitizer	Same
In Vitro Cytotoxicity test ISO 10993-5	Passed Under conditions of the study, device extract is non-cytotoxic	Passed Under conditions of the study, device extract is non-cytotoxic	Same

[1.] The subject device sizes ranges from XS – XXL, whereas the predicate device size ranges from XS-XL. the predicate device. All sizes for the subject device meet the requirements of ASTM D6319-19.

11. Discussion of Non-Clinical Tests:

Summary of Non-Clinical Testing

- **Biocompatibility**

  Biocompatibility Testing was performed according to the following tests for the subject device to evaluate the biocompatibility of Nitrile Patient Examination Gloves, Powder Free, Pink Color

  - ISO 10993-10:2010 Biological Evaluation of Medical Devices -Part 10: Tests for Irritation and Skin Sensitization.
  - ISO 10993-5:2009 Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity

- **Performance Testing**

  Physical performance testing of the proposed device was conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves.*

  To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

  - ASTM D6319-19 Standard Specification for *Nitrile Examination Gloves*.
  - ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
  - ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

Test Method	Purpose	Acceptance Criteria	Results
Dimensions (length) (width) (thickness) ASTM D6319-19	The purpose of the test is to evaluate the physical dimension of the glove	Length 220 mm min (XS, S) 230 mm min (M, L, XL, XXL)	Pass 240 mm min
		Width (mm) XS: 70±10 S: 80±10 M: 95±10 L：110±10 XL：120±10 XXL：130±10	Pass XS: average 78.4mm S: average 86.2mm M: average 97.4mm L： average 108.7mm XL： average 115.5mm XXL：average 123.5mm
		Thickness(mm): Palm:Minimum 0.05 Finger:Minimum 0.05	Pass Palm – 0.056mm min. Finger – 0.082mm min
Physical properties ASTM D6319-19	The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging	Before Aging: Tensile Strength: 14 MPa, min. Elongation: 500%, min. After Aging: Tensile Strength: 14 MPa, min. Elongation: 400%, min.	Pass Before Aging: Tensile Strength: 20.6MPa, min. Elongation: 531%, min. After Aging: Tensile Strength: 21.9MPa, min. Elongation: 416%, min.
Freedom from holes ASTM D5151-19	The purpose of the test is to detect holes in the gloves	No leakage at sampling level of G-1, AQL 2.5	Pass (Ac 14 Re 15) No leakage, 310 of 315 passed
Residual Powder ASTM D6124-06	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass Average 0.15 mg per glove
In Vitro Cytotoxicity Test ISO 10993-5	To determine the cytotoxic potential of the glove.	Under the conditions of the study, the device is not cytotoxic	Pass Under the conditions of the study, the device have no cytotoxic effect
Skin Sensitization Test ISO 10993-10	To determine the skin sensitization potential of the glove.	Under the conditions of the study, the device is not a sensitizer	Pass Under the conditions of the study, the device is not a sensitizer.

Skin Irritation Test ISO 10993-10	To determine the potential of the glove under test to produce irritation.	Under the conditions of the study, the device is not an irritant	Pass Under the conditions of the study, the device is not an irritant.

12. **Discussion of Clinical Tests:**
    Not Applicable

13. **Conclusion:**
    The conclusions drawn from the nonclinical tests demonstrate that Shandong YINGHONG Medical Products Co., Ltd. Nitrile Patient Examination Gloves, Powder Free, Pink Color is as safe, as effective, and performs as well as or better than the legally marketed device, Disposable Powder Free Nitrile Examination Glove, Pink Color by Ever Growth (Vietnam) Co., Ltd., cleared under K190942.