August 11, 2023

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

Re: K231408
Trade/Device Name: Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 11, 2023
Received: May 15, 2023

Dear Deze Wang:

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,

Bifeng Qian -S

BiFeng Qian, M.D., Ph.D
Assistant Director
DHT4B: Division of Infection Control
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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)*
K231408

Device Name
Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile

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.

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# 510(K) Summary

(As requirement by 21 CFR 807.92) K231408

*Date： August 8, 2023*

**A. Applicant:**

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**B. Device:**

Trade Name: Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile.
Common Name: Non-Powdered Patient Examination Glove

Regulatory Information
Classification Name: Non-Powdered Patient Examination Glove
Classification: Class I
Product code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital and Personal Use

**C. Predicate device:**

K221169
Name of the device： Nitrile Examination Gloves Powder Free-Black
Owner's Name： JR Engineering & Medical Technologies (M) Sdn. Bhd.
Classification: Class I
Product code: LZA
Regulation Number: 21 CFR 880.6250

**D. Indications for use of the device:**

The Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile is a disposable device intended for medical purposes that is worn on the examiners' hand or fingers to prevent contamination between patient and examiner.

**E. Device Description:**

The subject device is a patient examination glove made of synthetic nitrile latex compound. It is Non-Sterile, Powder free and is Blue in color. The device is ambidextrous and can be worn on either the left or right hand. The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility per ISO 10993-10, ISO 10993-11.

**F. Summary of Technological Characteristics**

The Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile are compared with the predicate device in terms of intended use, design, material, specifications, and performance.

The following table shows similarities and differences of use, design, and material between the proposed device and the predicate device.

Table 1 General Comparison of Proposed and Predicate Devices

| Device | Proposed Device | Predicate Device | Result |
|---|---|---|---|
| **510K #** | K231408 | K221169 | - |
| **Product Name** | Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile | JR MEDIC Nitrile Examination Gloves Powder Free- Black | - |
| **Manufacturer(s)** | Shandong Intco Medical Products Co., Ltd. | JR Engineering & Medical Technologies (M) SDN.BHD. | - |
| **Product Code** | LZA | LZA | Same |
| **Regulation Number** | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| **Indications for use** | The Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner. | Nitrile Examination Gloves Powder free is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. | Same |
| **Powder free** | Yes | Yes | Same |
| **Design feature** | Ambidextrous. | Ambidextrous. | Same |
| **Material** | Nitrile | Nitrile | Same |
| **Color** | Blue | Black | Different |
| **Size** | XS, S, M, L, XL, XXL | XS, S, M, L, XL | Similar |
| **Sterile** | Non-Sterile | Non-Sterile | Same |
| **Use** | Singe use | Single use | Same |

**Analysis:** The proposed device has product size XS, S, M, L, XL, XXL . while the predicate device has product size XS, S, M, L, XL. The proposed device is Blue color, while the predicate device is black color. But safety and performance testing has been done to the proposed device and the results showed that the device meets the requirements of standard ASTM D6319-19. Therefore, this difference do not raise any new safety or performance questions.

Table 2 Comparison of Physical, Biocompatibility and Performance Testing

| CHARACTERSTICS | STANDARDS | DEVICE PERFORMANCE | | Remarks |
|---|---|---|---|---|
| | | SUBJECT | PREDICATE | |
| 510(k) Number | | K231408 | K221169 | ---- |
| Name of device | | Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile | Nitrile Examination Gloves Powder Free-Black | ---- |
| Dimensions | ASTMD6319- 19 | Length Min 230 m<br>Width Min 95+/- 10 mm<br>( for medium size) | Length Min 230 mm<br>Width Min 95+/- 10 mm<br>(for medium size) | Same |
| Physical Properties | ASTMD6319- 19 | **Before Aging**<br>Tensile Strength<br>min 14 MPa<br>Ultimate Elongation<br>Min 500%<br>**After Aging**<br>Tensile Strength<br>min 14 MPa<br>Ultimate Elongation<br>Min 400% | **Before Aging**<br>Tensile Strength<br>min 14 MPa<br>Ultimate Elongation<br>Min 500%<br>**After Aging**<br>Tensile Strength<br>min 14 MPa<br>Ultimate Elongation<br>Min 400% | Same |
| Thickness | ASTMD6319- 19 | Palm min 0.05 mm<br>Finger min 0.05 mm | Palm min 0.05 mm<br>Finger min 0.05 mm | Same |
| Powder Free | ASTMD6319- 19 | ≤2 mg/glove | ≤2 mg/glove | Similar |
| Water leak | ASTM D5151-19 | 3/315 AQL2.5 | Meets ASTM D6319 requirements | Similar |
| Biocompatibility | Primary Skin Irritation-ISO 10993-10:2010 | Under the condition of study not an irritant | Under the condition of study not an irritant | Same |
| | Dermal Sensitization- ISO 10993- 10:2010 | Under the conditions of the study not a sensitizer | Under the conditions of the study not a sensitizer | Same |

| | | | |
|---|---|---|---|
| In vitro cytotoxicity ISO10993-5 :2009 | Data Not available | Under the conditions of the study, cytotoxic. | ------ |
| Acute Systemic Toxicity Test ISO 10993- 11:2017 | Under the conditions of this study, there was no evidence of systemic toxicity. | Under the condition of study the device extracts do not pose a systemic toxicity. | Same |

**Analysis:** The proposed device has the Skin Sensitization test, Primary Skin Irritation test and the Acute Systemic Toxicity test. The result is the same as the PREDICATE device's.

**G. Summary of Non-Clinical Testing**

➢ **Biocompatibility**

The following tests for the subject device were conducted to evaluate the biocompatibility of Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile:

- ISO 10993-10: Skin Sensitization test
- ISO 10993-10: Intracutaneous Reactivity test
- ISO 10993-11: Acute Systemic Toxicity test

➢ **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) | The purpose of the test is to evaluate the physical dimension of the glove | Length<br>230 mm min | Pass<br>240 mm min |
| | | Width(mm)<br>XS: 70±10<br>S: 80±10<br>M: 95±10<br>L: 110±10<br>XL: 120±10<br>XXL: 130±10 | Pass<br>XS: average 78.3mm<br>S: average 86.5mm<br>M: average 97.6mm<br>L: average 108.7mm<br>XL: average 115.4mm<br>XXL: average 123.7mm |
| | | Thickness(mm):<br>Palm: Minimum 0.05 | Pass<br>Palm – 0.06mm min. |

| | | | |
|---|---|---|---|
| | | Finger: Minimum 0.05 | Finger – 0.082mm min |
| Physical properties | The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging | Before Aging:<br>Tensile Strength: 14 MPa, min.<br>Elongation: 500%, min.<br>After Aging:<br>Tensile Strength: 14 MPa, min.<br>Elongation: 400%, min. | Pass<br>Before Aging:<br>Tensile Strength: 22.6MPa, min.<br>Elongation: 531%, min.<br>After Aging:<br>Tensile Strength: 21.9MPa, min.<br>Elongation: 437%, min. |
| Freedom from holes | The purpose of the test is to detect holes in the gloves | No leakage at sampling level of G-1, AQL 2.5 | Pass<br>No leakage, 312 of 315 passed |
| Residual Powder | The purpose of the test is to detect the powder residue in the glove | <2mg per glove | Pass<br>average 0.17 mg per glove |

**H. Clinical Test Conclusion**

No clinical study is included in this submission.

**I. Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Basic Synguard Nitrile Exam Gloves, Powder Free, Blue Colored, Non-Sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K221169.