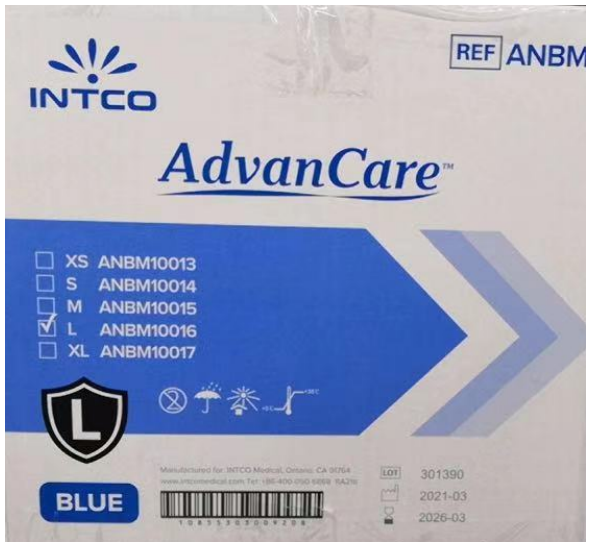
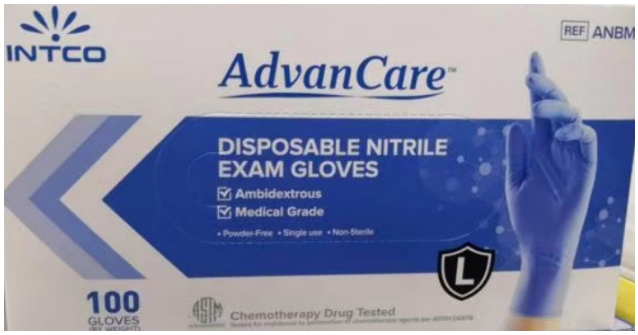
# INTCO AdvanCare Medical Exam Chemo Gloves

Blue | Medical Grade | Powder Free | FDA 510(k) | Latex Free




New Search | Back To Search Results

| | |
|---|---|
| **Device Classification Name** | Polymer Patient Examination Glove |
| **510(K) Number** | K200093 |
| **Device Name** | Synthetic Nitrile Patient Exam Gloves, Powder Free, Blue, Tested For Use W/Chemotherapy Drug |
| **Applicant** | Anhui Lntco Medical Products Co., Ltd.<br>No. 1 Haitang Road, Suixi District Economic Development Area<br>Huaibei City, CN 235100 |
| **Applicant Contact** | Jacken Cai |
| **Correspondent** | Lntco Medical Industries, Inc.<br>805 Barrington Ave<br>Ontario, CA 91764 |
| **Correspondent Contact** | Jason Ji |
| **Regulation Number** | 880.6250 |
| **Classification Product Code** | LZA |
| **Subsequent Product Code** | LZC |
| **Date Received** | 01/16/2020 |
| **Decision Date** | 08/20/2020 |
| **Decision** | Substantially Equivalent (SESE) |
| **Regulation Medical Specialty** | General Hospital |
| **510k Review Panel** | General Hospital |
| **Statement** | Statement |
| **Type** | Traditional |
| **Reviewed By Third Party** | No |
| **Combination Product** | No |

August 20, 2020

Anhui lntco Medical Products Co., Ltd.
℅ Jason Ji
Official Correspondent
lntco Medical Industries, Inc.
805 Barrington Ave
Ontario, California 91764

Re: K200093
Trade/Device Name: Synthetic Nitrile Patient Exam Gloves, Powder Free, Blue, Tested for Use w/Chemotherapy Drug
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: May 16, 2020
Received: Jun 02, 2020

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,

Elizabeth F. Claverie -S

CAPT Elizabeth Claverie, M.S.
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)*
K200093

Device Name
Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

The synthetic nitrile patient examination gloves, powder free, blue color and tested for use with chemotherapy drugs are disposable devices intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. The glove was tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

| Chemotherapy Drug and Concentration | Breakthrough Detection Time in Minutes |
|---|---|
| Blenoxane (Bleomycin), 15 mg/ml (15,000 ppm) | >240 |
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 22.6 |
| Cyclophosphamide, 20 mg/ml (20,000 ppm) | >240 |
| Cytarabine, 100 mg/ml (100,000 ppm) | >240 |
| Etoposide (Toposar), 20 mg/ml (20,000 ppm) | >240 |
| Fluorouracil (5 Flu), 50 mg/ml (50,000 ppm) | >240 |
| Idarubicin, 1 mg/ml (1,000 ppm) | >240 |
| Mesna, 100 mg/ml (100,000 ppm) | >240 |
| Mitomycin C, 0.5 mg/ml (500 ppm) | >240 |
| Paclitaxel, 6 mg/ml (6,000 ppm) | >240 |
| Thiotepa, 10 mg/ml (10,000 ppm) | 46.9 |
| Trisenox, 1 mg/ml (1,000 ppm) | >240 |
| Vincristine Sulfate, 1 mg/ml (1,000 ppm) | >240 |

1. CAUTION: Testing showed an average breakthrough time of 46.9 minutes with Thiotepa and 22.6 minutes with Carmustine
2. WARNING: Do not use with Carmustine.

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."*

## 1.0 产品信息 Product information

一次性丁腈检查手套
Disposable Nitrile Examination Gloves
尺寸：XS, S, M, L, XL
Size：XS, S, M, L, XL
粉量：无粉
Powder free
非灭菌
No sterile

## 2.0 尺寸规格 Dimension

### 2.1 基本尺寸 Typical dimensions

| 型号 Size | XS | S | M | L | XL | 检查水平 Inspection level | 接收限 AQL |
|---|---|---|---|---|---|---|---|
| 长度 mm Length | Min.220 | | Min.230 | | | S-2 | 4.0 |
| 掌宽 mm Width | 70±10 | 80±10 | 95±10 | 110±10 | 120±10 | | |

### 2.2 克重与厚度 Weight & thickness

克重 Weight M 3.0g

| 型号 Size | XS | S | M | L | XL | 检查水平 Inspection level | 接收限 AQL |
|---|---|---|---|---|---|---|---|
| 克重 g Weight | 2.8±0.3 | 2.8±0.3 | 3.0±0.3 | 3.4±0.3 | 3.8±0.3 | S-2 | 4.0 |
| 指尖厚度 mm Finger thickness | 0.09±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm Palm thickness | 0.08±0.03 | | | | | | |
| 腕部厚度 mm Cuff thickness | 0.07±0.03 | | | | | | |

克重 Weight M 3.5g

| 型号 Size | XS | S | M | L | XL | 检查水平 Inspection level | 接收限 AQL |
|---|---|---|---|---|---|---|---|
| 克重 g Weight | 3.0±0.3 | 3.0±0.3 | 3.5±0.3 | 3.9±0.3 | 4.3±0.3 | S-2 | 4.0 |
| 指尖厚度 mm Finger thickness | 0.10±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm Palm thickness | 0.08±0.03 | | | | | | |
| 腕部厚度 mm Cuff thickness | 0.07±0.03 | | | | | | |

克重 Weight M 4.0g

| 型号 Size | XS | S | M | L | XL | 检查水平 Inspection level | 接收限 AQL |
|---|---|---|---|---|---|---|---|
| 克重 g Weight | 3.5±0.3 | 3.5±0.3 | 4.0±0.3 | 4.4±0.3 | 4.8±0.3 | S-2 | 4.0 |
| 指尖厚度 mm Finger thickness | 0.11±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm Palm thickness | 0.08±0.03 | | | | | | |
| 腕部厚度 mm Cuff thickness | 0.07±0.03 | | | | | | |

克重 Weight M 4.5g

| 型号 Size | XS | S | M | L | XL | 检查水平 Inspection level | 接收限 AQL |
|---|---|---|---|---|---|---|---|
| 克重 g Weight | 4.0±0.3 | 4.0±0.3 | 4.5±0.3 | 4.9±0.3 | 5.3±0.3 | S-2 | 4.0 |
| 指尖厚度 mm Finger thickness | 0.12±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm Palm thickness | 0.09±0.03 | | | | | | |
| 腕部厚度 mm Cuff thickness | 0.08±0.03 | | | | | | |

克重 Weight M 5.0g

| 型号<br>Size | XS | S | M | L | XL | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|---|---|---|---|
| 克重 g<br>Weight | 4.5±0.3 | 4.5±0.3 | 5.0±0.3 | 5.4±0.3 | 5.8±0.3 | S-2 | 4.0 |
| 指尖厚度 mm<br>Finger thickness | 0.13±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm<br>Palm thickness | 0.09±0.03 | | | | | | |
| 腕部厚度 mm<br>Cuff thickness | 0.08±0.03 | | | | | | |

克重 Weight M 5.5g

| 型号<br>Size | XS | S | M | L | XL | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|---|---|---|---|
| 克重 g<br>Weight | 5.0±0.3 | 5.0±0.3 | 5.5±0.3 | 5.9±0.3 | 6.3±0.3 | S-2 | 4.0 |
| 指尖厚度 mm<br>Finger thickness | 0.14±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm<br>Palm thickness | 0.10±0.03 | | | | | | |
| 腕部厚度 mm<br>Cuff thickness | 0.09±0.03 | | | | | | |

克重 Weight M 6.0g

| 型号<br>Size | XS | S | M | L | XL | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|---|---|---|---|
| 克重 g<br>Weight | 5.5±0.3 | 5.5±0.3 | 6.0±0.3 | 6.4±0.3 | 6.8±0.3 | S-2 | 4.0 |
| 指尖厚度 mm<br>Finger thickness | 0.16±0.03 | | | | | S-2 | 4.0 |
| 掌心厚度 mm<br>Palm thickness | 0.10±0.03 | | | | | | |
| 腕部厚度 mm<br>Cuff thickness | 0.09±0.03 | | | | | | |

## 3.0 物理性能 Physical Characters

对于所有尺寸：XS, S, M, L, XL

For all sizes: XS, S, M, L, XL

| 阶段<br>Phase | 项目<br>Item | 标准值<br>Values | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|---|
| 老化前<br>Before aging | 拉断强度<br>Tensile Strength | Min.14 MPa | S-2 | 4.0 |
| | 拉断延伸率<br>Ultimate Elongation | Min.500% | | |
| 老化后<br>After aging | 拉断强度<br>Tensile Strength | Min.14 MPa | | |
| | 拉断延伸率<br>Ultimate Elongation | Min.400% | | |

## 4.0 针孔 Pin holes

对于所有尺寸：XS, S, M, L, XL

For all sizes: XS, S, M, L, XL

| 项目<br>Item | 标准<br>Standard | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|
| 针孔<br>Freedom from holes | No water leakage | G-1 | 2.5 |

## 5.0 外观 Visual inspection

对于所有尺寸：XS, S, M, L, XL

For all sizes: XS, S, M, L, XL

| 项目<br>Item | 分类<br>Classification | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|
| 外观<br>Visual inspection | 严重缺陷<br>Critical defect | S-4 | 1.0 |
| | 重要缺陷<br>Major defect | | 2.5 |
| | 轻微缺陷<br>Minor Defect | | 4.0 |

## 6.0 粉量 Powder-free Residue

对于所有尺寸：XS, S, M, L, XL

For all sizes: XS, S, M, L, XL

| 项目<br>Item | 标准值<br>Values | 检查水平<br>Inspection level | 接收限<br>AQL |
|---|---|---|---|
| 粉量 Power | Max.2.0mg | N=5 | N/A |

## 7.0 其它 Others

本产品符合 ASTM D7160 标准要求，有效期 5 年。

The product meets the standard of ASTM D7160, and the shelf life is 5 years.