March 1, 2024

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

Re: K231365
Trade/Device Name: Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, aka Synguard C+ Nitrile Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: January 3, 2024
Received: January 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 and Reconstructive 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)*
K231365

Device Name
Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate, aka Synguard C+ Nitrile Exam Gloves

Indications for Use *(Describe)*

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine (BCNU)(3.3 mg/ml)	12.1 min.
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240 min.
Doxorubicin Hydrichloride (2.0mg/)	>240 min.
Etoposide (Toposar) (20.0mg/ml)	>240 min.
Fluorouracil (50.0mg/ml)	>240 min.
Methotrexate (25.0 mg/ml)	>240 min.
Paclitaxel (Taxol) (6.0 mg/ml)	>240 min.
Thiotepa(10.0 mg/ml)	10.1 min.
Vincristine Sulfate(1.0 mg/ml)	>240 min.
Cisplatin(1.0 mg/ml)	>240 min.
Dacarbazine(10 mg/ml)	>240 min.
Mitomycin C(0.5 mg/ml)	>240 min.

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 12.1 minutes and Thiotepa:10.1 minutes.
Warning: Do not use with Carmustine or Thiotepa

Fentanyl Citrate & Concentration	Minimum Breakthrough Detection Times
Fentanyl Citrate Injection(100 mcg/2ml)	>240 min.

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.6 Haitang South Road, Suixi, Anhui, China

510(K) SUMMARY K231365

(As requirement by 21 CFR 807.92)

1. Submitter's Identification:

Anhui Intco Medical Products Co, ltd.
No.6 Haitang South Road, Suixi Wuhu Modern Industrial Park Suixi County，
Huaibei City, Anhui Province,China

Contact Person：

Max Li Tel: 86-18918364816

Date summary prepared: March 1, 2024

2. Product Trade Name:

Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate.
Aka Synguard C+ Nitrile Exam Gloves

3. Device Classification Name:

Patient Examination gloves (21 CFR 880.6250)

4. Device Class:

Class I.

5. Product Code:

LZA, LZC,OPJ,QDO.

6. Predicate Devices:

K200671 – Ansell Healthcare Products LLC Powder-Free Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl

7. Reason for 510(k) Submission:

New device.

8. Device Description:

The Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate. Aka Synguard C+ Nitrile Exam Gloves are non-sterile, single

use only, disposable, powder free examination gloves. The glove is made of nitrile butadiene rubber. Chlorination is applied to the inner surface of the glove to make donning easy.

Characteristic:

- Ambidextrous with beaded cuff and straight fingers
- Finger-textured,
- Blue colored
- Containing Hyaluronic Acid coating.
- Six (6) sizes – extra-small, small, medium, large, extra-large and XXL.
- Tested against chemotherapy drugs and fentanyl citrate.

The gloves are designed to meets the specifications of ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

9. Indications for Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Carmustine (BCNU)(3.3 mg/ml)	12.1 min.
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240 min.
Doxorubicin Hydrichloride (2.0mg/)	>240 min.
Etoposide (Toposar) (20.0mg/ml)	>240 min.
Fluorouracil (50.0mg/ml)	>240 min.
Methotrexate (25.0 mg/ml)	>240 min.
Paclitaxel (Taxol) (6.0 mg/ml)	>240 min.
Thiotepa(10.0 mg/ml)	10.1 min.
Vincristine Sulfate(1.0 mg/ml)	>240 min.
Cisplatin(1.0 mg/ml)	>240 min.
Dacarbazine(10 mg/ml)	>240 min.
Mitomycin C(0.5 mg/ml)	>240 min.

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 12.1 minutes and Thiotepa:10.1 minutes.

Warning: Do not use with Carmustine or Thiotepa

Fentanyl Citrate & Concentration	Minimum Breakthrough Detection Times
Fentanyl Citrate Injection(100 mcg/2ml)	>240 min.

10. Technological Characteristics Comparison Table:

Characteristics	Acceptance Criteria	Anhui Intco Medical Products Co., Ltd. Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate	Ansell Healthcare Products LLC Powder-Free Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl	Comparison Conclusions

K-Number		K231365	K200671	
Product Code	LZA,LZC,OPJ,QDO	LZA,LZC,OPJ,QDO	LZA, LZC,QDO	
Intended use	/	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Same
Material used	Nitrile	Nitrile	Nitrile	Identical
Color	Blue	Blue	Blue	Same
Single use	Single Use	Yes	Yes	Same
Non Sterile	Non Sterile	Non Sterile	Non Sterile	Same
Other	/	Hyaluronic Acid coated on the donning surface	Aloe and Chamomile coated on the donning surface	Different①
Dimensions	Overall Length (mm) For XS，S,Min 220mm For M,L,XL,XXL Min 230mm Width (± 10mm) Size XS = 70mm Size S = 80mm Size M = 95mm Size L = 110mm Size XL = 120mm Size XXL = 130mm Thickness at Palm (mm) Min; 0.05mm Thickness at Finger Tip (mm) Min 0.05 mm	Complies with ASTM D6319-19 X Small 70±10 Small 80 ±10 Medium 95±10 Large 110 ±10 X large 120 ±10 XX Large 130 ±10 Thickness Palm - 0.05mm min. Finger - 0.05 mm min.	Complies with ASTM D6319-10 X Small 75±5 Small 85 ±5 Medium 95±5 Large 105 ±5 X large 115 ±5 XX Large N/A Thickness Palm - 0.06mm min. Finger - 0.09 mm min	Similar

Physical properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	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 16 MPa, min. After Aging 14 MPa, min. Elongation: Before Aging 500% min. After Aging 400% min.	Meets the criteria
Freedom from pinholes	AQL 2.5 Inspection Level G-1	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 , AQL 2.5	Meets the criteria
Residual Powder	Less than 2mg per glove ASTM D 6124-06	Average power residue < 2mg per glove	Average powder residue ≤ 2mg per glove	Meets the criteria
-Primary Skin Irritation Test	ISO10993-10:2010	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, not an irritant.	Same
Dermal Sensitization Assay	ISO10993-10:2010	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, not a sensitizer.	Same
Acute systemic toxicity	ISO 10993-11:2017	Under the conditions of this study,No evidence of acute systemic toxicity	Under the conditions of this study,No evidence of acute systemic toxicity	Same
Resistance against Chemotherapy Drugs	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs	1) Carmustine (BCNU) (3.3 mg/ml), Breakthrough time: 12.1 min. 2) Cyclophosphamide	1) Carmustine (BCNU) (3.3 mg/ml), Breakthrough time: 17.4 min.	Similar

	ASTM D6978-05(2013)	(Cytoxan), (20.0 mg/ml), Breakthrough time: >240 min. 3) Doxorubicin Hydrochloride (2.0mg/), Breakthrough time: >240 min. 4) Etoposide (Toposar) (20.0mg/ml), Breakthrough time: >240 min. 5) Fluorouracil (50.0mg/ml), Breakthrough time:>240 min. 6) Methotrexate (25.0 mg/ml), Breakthrough time: >240 min. 7) Paclitaxel (Taxol) (6.0 mg/ml), Breakthrough time: >240 min. 8) Thiotepa Breakthrough time: 10.1 min. 9) Vincristine Sulfate (1.0 mg/ml), Breakthrough time:>240 min. 10) Cisplatin (1.0 mg/ml), Breakthrough time:>240 min. 11) Dacarbazine (10 mg/ml), Breakthrough time:>240 min. 12) Mitomycin C (0.5 mg/ml), Breakthrough time:>240 min. 13）Fentanyl Citrate Injection (100 mcg/2ml), Breakthrough time:>240 min.	2) Cyclophosphamide (Cytoxan), (20.0 mg/ml), Breakthrough time: >240 min. 3) Doxorubicin Hydrochloride (2.0mg/), Breakthrough time: >240 min. 4) Etoposide (Toposar) (20.0mg/ml), Breakthrough time: >240 min. 5) 6) Fluorouracil (50.0mg/ml), Breakthrough time:>240 min. 6) Methotrexate (25.0 mg/ml), Breakthrough time: >240 min. 7) Paclitaxel (Taxol) (6.0 mg/ml), Breakthrough time: >240 min. 8) Thiotepa Breakthrough time: 67.1 min. 9)Vincristine Sulfate (1.0 mg/ml), Breakthrough time:>240 min.	

Analysis ①: The proposed device added the Hyaluronic Acid. while the predicate device added the Aloe and Chamomile, they are not the animal derived. Biocompatibility testing is the same, and the 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 does not raise any new safety or performance questions.

11. Non-clinical Testing

The following non-clinical tests were performed:

- ASTM D6319-19 Standard Specification for Nitrile examination Gloves for Medical Application.
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.
- ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
- ISO 10993-23 First Edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.
- ISO 10993-10 Fourth Edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.
- ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.
- ISO 10993-11 Third Edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.

12. Clinical Testing

N/A.

13. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that Anhui Intco Medical Products Co., Ltd. Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device K200671, Ansell Healthcare Products LLC Powder-Free Microflex® Nitrile Patient Examination Gloves with Aloe and Chamomile Pink Colored Tested for Use with Chemotherapy Drugs and Fentanyl.