November 28, 2023

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

Re: K232252
Trade/Device Name: Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: October 26, 2023
Received: October 30, 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 (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,

Bifeng Qian -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232252

Device Name
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange).

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.
These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drugs and Fentanyl Concentration	Minimum Breakthrough Detection Time (minutes) Black	Orange
*Carmustine 3.3mg/ml (3,300 ppm)	21.6	22.7
Cyclophosphamide 20 mg/ml (20.000 ppm)	>240 min.	>240 min.
Doxorubicin HCl 2 mg/ml (2,000 ppm)	>240 min.	>240 min.
Etoposide 20mg/ml (20,000 ppm)	>240 min.	>240 min.
Fluorouracil 50 mg/ml(50,000 ppm)	>240 min.	>240 min.
Mitomycin C 50 mg/ml(500 ppm)	>240 min.	>240 min.
Oxaliplatin 5 mg/ml (5,000 ppm)	>240 min.	>240 min.
Paclitaxel 6 mg/ml (6,000 ppm)	>240 min.	>240 min.
*Thiotepa 10 mg/ml (10,000 ppm)	28	37.1
Fentanyl Citrate Injection 100mcg/2mL	>240 min.	>240 min.

*Please note that following drugs have extremely low permeation times:
1. Carmustine (BCNU)
2. Thio Tepa
Warning: Do not use with Carmustine and Thiotepa

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.

510(K) SUMMARY K232252

(As requirement by 21 CFR 807.92)

Applicant Name	Dehai (Shandong) Medical Gloves, Co., Ltd.
Location	No. 216 Huagong Road Linzi District, Zibo City, Shandong Province, China
Contact Person:	Li xiaomeng
Tel:	+86-13917372099

Date summary prepared: 16th Nov. 2023

Device Information

Trade Name:	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange)
Common Name:	POWDER FREE NITRILE EXAMINATION GLOVES
Classification Name:	Non- Powdered Patient Examination Gloves
Product Code:	LZA, LZC, QDO, OPJ
Regulation:	21CFR:880 . 6250

Predicate Device

NITRILE EXAMINATIONGLOVES POWDERFREE TESTED FOR USE WITH CHEMOTHERAPY DRUGS & FENTANYL CITRATE(BLUE & BLACK), 510(K) number K230121 product code LZA, LZC, QDO, OPJ.

Device Description

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange) are made from synthetic rubber latex. It is single use and powder- free. The subject device is a patient examination glove made from nitrile latex compound, Black and Orange color, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves. The available sizes are Small, Medium, Large ,X-Large and XX-Large. The Nitrile Examination Gloves Powder Free (Black & Orange) have been tested for Chemotherapy Drugs and Fentanyl Citrate as below:

Chemotherapy Drugs and Fentanyl	Concentration	Minimum Breakthrough Detection Time (minutes)	
		Black	Orange
* Carmustine	3.3mg/ml (3,300 ppm)	21.6	22.7
Cyclophosphamide	20 mg/ml (20.000 ppm)	>240 min.	>240 min.
Doxorubicin HCl	2 mg/ml (2,000 ppm)	>240 min.	>240 min.
Etoposide	20mg/ml (20,000 ppm)	>240 min.	>240 min.
Fluorouracil	50 mg/ml(50,000 ppm)	>240 min.	>240 min.
Mitomycin C	50 mg/ml(500 ppm)	>240 min.	>240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	>240 min.	>240 min.
Paclitaxel	6 mg/ml (6,000 ppm)	>240 min.	>240 min.
* Thiotepa	10 mg/ml (10,000 ppm)	28	37.1
Fentanyl Citrate Injection	100mcg/2mL	>240 min.	>240 min.

* Please note that following drugs have extremely low permeation times:
1. Carmustine (BCNU)
2. Thio Tepa

Warning: Do not use with Carmustine and Thiotepa

Indications for Use

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.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drugs and Fentanyl	Concentration	Minimum Breakthrough Detection Time (minutes)	
		Black	Orange
* Carmustine	3.3mg/ml (3,300 ppm)	21.6	22.7
Cyclophosphamide	20 mg/ml (20.000 ppm)	>240 min.	>240 min.
Doxorubicin HCl	2 mg/ml (2,000 ppm)	>240 min.	>240 min.
Etoposide	20mg/ml (20,000 ppm)	>240 min.	>240 min.
Fluorouracil	50 mg/ml(50,000 ppm)	>240 min.	>240 min.
Mitomycin C	50 mg/ml(500 ppm)	>240 min.	>240 min.
Oxaliplatin	5 mg/ml (5,000 ppm)	>240 min.	>240 min.
Paclitaxel	6 mg/ml (6,000 ppm)	>240 min.	>240 min.
* Thiotepa	10 mg/ml (10,000 ppm)	28	37.1
Fentanyl Citrate Injection	100mcg/2mL	>240 min.	>240 min.

* Please note that following drugs have extremely low permeation times:
1. Carmustine (BCNU)
2. Thio Tepa

Warning: Do not use with Carmustine and Thiotepa

Summary of The Technological Characteristic

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black), Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Orange), are summarized with the following technological characteristic compared to ASTM D6319 or equivalent standards.

Characteristic	Standard	Subject Device K232252	Predicate Device K230121	Remarks
Product Code	-	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Intended Use	-	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Same
Design	-	Powder Free, Non-Sterile, Ambidextrous, Beaded Cuff	Powder Free, Non-Sterile, Ambidextrous, Beaded Cuff	Same
Indications for Use	-	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. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	A 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. These gloves were 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.	Same
Construction	-	Ambidextrous Chlorinated, Powder Free Nitrile	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Similar
Color Description	-	Black & Orange	Blue & Black	Different
Material	-	Nitrile	Nitrile	Similar
Single Use	-	Yes	Yes	Same
Packaging	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same
Chemo Drugs Claim	-	Chemo Drugs & Fentanyl Citrate claim	Chemo Drugs & Fentanyl Citrate claim	Similar
Sterility	-	Non-Sterile	Non-Sterile	Same
Dimension Length S, M, L, XL, XXL Thickness (palm), Thickness (finger), Width	ASTM D6319- 19	Meet 220mm min for S Meet 230mm min for other sizes Meet 0.05mm min Meet 0.05mm min S: Meet 80 ± 10 mm M: Meet 95 ± 10 mm L: Meet 110 ± 10 mm XL: Meet 120 ± 10 mm XXL: Meet 130 ± 10 mm	Meet 220mm min for small Meet 230mm min for other sizes Meet 0.05mm min Meet 0.05mm min S: Meet 80 ± 10 mm M: Meet 95 ± 10 mm L: Meet 110 ± 10 mm XL: Meet 120 ± 10 mm	Similar Similar Similar

Characteristic	Standard	Subject Device K232252	Predicate Device K230121	Remarks
Physical Properties (Before Ageing) i) Tensile Strength (MPa) ii) Ultimate Elongation (%) (After Aging) i) Tensile Strength (MPa) ii) Ultimate Elongation (%)	ASTM D6319- 19	Meet 14MPa min. Meet 500% min Meets 14MPa min Meet 400% min.	Meet 14MPa min. Meet 500% min Meets 14MPa min Meet 400% min.	Same Same
Water Leak Test, 1000 ml Before Aging, AQL	ASTM D6319- 19 ASTM D5151-19	Passes at AQL 2.5 Meet the ASTM D 6319-19 requirement	Passes at AQL 1.5	Different
Powder Free Residue Powder Free Residue, mg/ glove	ASTM D6319- 19 ASTM D6124-06	Meet 2mg/glove max.	Meet 2mg/glove max.	Same
Biocompatibility Test i) Primary Skin Irritation Test	ISO 10993-23 new version (ISO 10993- 10)	Passes Conclusion: The test result showed that the response of the test article was categorized as negligible under the test condition	Passes Conclusion: Under the conditions of this study the test material did not cause an irritant response	Similar
ii) Skin Sensitization Test	ISO 10993- 10	Passes Conclusion: Under the conditions of this study, the test article showed no significant evidence of causing skin sensitization in the guinea pig	Passes Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	Similar
iii) Acute Systemic Toxicity	ISO 10993- 11	Conclusion: Under the conditions of this study, there was no evidence of acute systemic toxicity from the extract. The test article extract met the requirements of the study.	Conclusion: Under condition. of this study, the test material showed no adverse biological reaction after administration of the sample's extract on the rats during the period of the study.	Similar

Summary of Non-Clinical Testing

Following is a table showing the actual measured parameters of the gloves (e.g length, thickness, physical properties, etc.) as compared to ASTM, EN and ISO. All data meets the standard reference requirement.

Black color			
Test	Method	Acceptance Criteria	Result
Freedom From Holes	ASTM D6319-19 ASTM D5151-19	Meet requirement inspection level G- 1, AQL 2.5 Sampling size125pcs(Ac: 7,Re: 8)	Pass ≤3pcs
Dimension	ASTM D6319-19	Length 220 mm min (small) 230 mm min (other sizes)	Pass 241 mm min
		Width(mm) S: 80±10 M: 95±10 L : 110±10 XL : 120±10 XXL : 130±10	Pass S: average 85.5mm M: average 96.3mm L : average 106.4mm XL : average 115.5mm XXL : average 125.1mm
		Thickness(mm): Palm: Minimum 0.05 Finger: Minimum 0.05	Pass Palm – 0.178mm min. Finger–0.199mm min
Physical properties	ASTM D6319-19	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: 15.1 MPa, min. Elongation: 518%, min. After Aging: Tensile Strength: 15.0MPa, min. Elongation: 460%, min.
Residual Powder Content	ASTM D6319-19 ASTM D6124-06	Not more than 2 mg per glove	Pass average 0.32mg
Biocompatibility i) Primary Skin Irritation ii) Skin Sensitization iii) Acute Systemic Toxicity	 ISO 10993-23 ISO 10993-10 ISO 10993-11	 Not a primary skin irritant Not a contact sensitizer No systemic toxicity	 Pass Pass Pass
Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (minutes)	Remark

Orange color			
Test	Method	Acceptance Criteria	Result
Freedom From Holes	ASTM D6319-19 ASTM D5151-19	Meet requirement inspection level G- 1, AQL 2.5 Sampling size125pcs(Ac: 7,Re: 8)	Pass ≤4pcs
Dimension	ASTM D6319-19	Length 220 mm min (small) 230 mm min (other sizes)	Pass 240 mm min
		Width(mm) S: 80±10 M: 95±10 L : 110±10 XL : 120±10 XXL : 130±10	Pass S: average 85.8mm M: average 96.1mm L : average 106.8mm XL : average 115.9mm XXL : average 125.6mm
		Thickness(mm): Palm:Minimum 0.05 Finger:Minimum 0.05	Pass Palm – 0.181mm min. Finger–0.212mm min
Physical properties	ASTM D6319-19	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: 15.3 MPa, min. Elongation: 502%, min. After Aging: Tensile Strength: 14.1MPa, min. Elongation: 462%, min.
Residual Powder Content	ASTM D6319-19 ASTM D6124-06	Not more than 2 mg per glove	Pass average 0.30mg
Biocompatibility			
i) Primary Skin Irritation	ISO 10993-23	Not a primary skin irritant	Pass
ii) Skin Sensitization	ISO 10993-10	Not a contact sensitizer	Pass
iii) Acute Systemic Toxicity	ISO 10993-11	No acute systemic toxicity	Pass
Chemotherapy Drug and Fentanyl	Concentration	Minimum Breakthrough Detection Time (minutes)	Remark

		Proposed Device		Predicate Device		
		Black	Orange	Blue	Black	
* Carmustine (BCNU)	3.3 mg/ml	21.6	22.7	22.6	21.8	Different
Cyclophosphamide	20.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Etoposide	20.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Fluorouracil	50.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Paclitaxel	6.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
* Thio Tepa	10.0 mg/ml	28	37.1	43.9	17.7	Different
Mitomycin C	0.5mg/ml	>240 min	>240 min	Not test	Not test	Different
Oxaliplatin	5mg/ml	>240 min	>240 min	Not test	Not test	Different
Dacarbazine	10.0 mg/ml	Not test	Not test	>240 min	>240 min	Different
Ifosfamide	50.0 mg/ml	Not test	Not test	>240 min	>240 min	Different
Cisplatin	1.0 mg/ml	Not test	Not test	>240 min	>240 min	Different
Mitoxantrone	2 mg/ml	Not test	Not test	>240 min	>240 min	Different
Vincristine Sulfate	1.0 mg/ml	Not test	Not test	>240 min	>240 min	Different
Fentanyl Citrate	100mcg/2ml	>240 min	>240 min	>240 min	>240 min	Same
Warning		Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) (3.3 mg/ml) 2. Thio Tepa (10 mg/ml)		*Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) (3.3 mg/ml) 2. Thio Tepa (10 mg/ml)		Similar

Summary of Clinical Testing

Not applicable.

CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K230121,Nitrile Examination Gloves Powder Free Tested For Use With Chemotherapy Drugs & Fentanyl Citrate (Blue & Black)