



January 26, 2024

Anhui Intco Medical Products Co., Ltd.
Max Li
Quality Specialist
No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park
Suixi County
Huaibei City, Anhui 235000
China

Re: K233598

Trade/Device Name: Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested
for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs

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: November 9, 2023

Received: November 9, 2023

Dear Max Li:

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

Indications for Use

510(k) Number (if known)
K233598

Device Name

Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs

Indications for Use (Describe)

Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs 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, Fentanyl Citrate, and Select Other Drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Test Chemotherapy drug & Concentration	Minimum Breakthrough Detection Times (Minutes)
Bendamustine HCl ; 5 mg/ml	>240
Bleomycin sulfate ; 15 mg/ml	>240
Busulfan ; 6 mg/ml	>240
Carboplatin ;10 mg/ml	>240.
Carfilzomib ; 2 mg/ml	>240
Carmustine ; 3.3 mg/ml	1.7
Cetuximab ; 2 mg/ml	>240
Cisplatin ; 1 mg/ml	>240
Cladribine ; 1 mg/ml	>240
Cyclophosphamide ; 20 mg/ml	>240
Cytarabine (Cytosine) ; 100 mg/ml	>240
Cytovene (Ganciclovir) ; 10 mg/ml	>240
Dacarbazine ; 10 mg/ml	>240
Daunorubicin HCL ; 5 mg/ml	>240
Decitabine ; 5 mg/ml	>240
Docetaxel ; 20 mg/ml	>240
Doxorubicin HCL ; 2 mg/ml	>240
Epirubicin HCL ; 2 mg/ml	>240
Etoposide ; 20 mg/ml	>240
Fludarabine Phosphate; 25 mg/ml	>240
Fluorouracil ; 50 mg/ml	>240
Fulvestrant ; 50 mg/ml	>240
Gemcitabine HCl ; 38 mg/ml	>240
Idarubicin HCl ; 1 mg/ml	>240
Ifosfamide ; 50 mg/ml	>240
Irinotecan HCl ; 20 mg/ml	>240
Mechlorethamine HCL ; 1 mg/ml	>240
Melphalan HCl; 5 mg/ml	>240
Methotrexate ; 25 mg/ml	>240
Mitomycin C ; 0.5 mg/ml	>240
Mitoxantrone HCl ; 2 mg/ml	>240
Oxaliplatin ; 5 mg/ml	>240
Pacilitaxel ; 6 mg/ml	>240

Pemetrexed ; 25 mg/ml	>240
Rituximab ; 10 mg/ml	>240
ThioTepa ; 10 mg/ml	0
Topotecan HCL ; 1 mg/ml	>240
Trisonex ; 1 mg/ml	>240
Velcade (Bortezomib) ; 1 mg/ml	>240
Vidaza (Azacytidine) ; 25 mg/ml	>240
Vincristine Sulfate ; 1 mg/ml	>240
Vinorelbine Tartrate; 10 mg/ml	>240
Zoledronic Acid ; 0.8 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 1.7 minutes and Thiotepa:0 minute

Warning: Do not use with Carmustine and Thiotepa

Fentanyl Citrate & Other Drugs

Minimum Breakthrough Detection Times

Fentanyl Citrate Injection(100 mcg/2ml)	>240
Chloroquine ; 50mg/ml	>240
Cyclosporin A; 100mg/ml	>240
Retrovir ; 10 mg/ml	>240

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 Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, China

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510(K)SUMMARY

(As required by 21 CFR 807.92)

K233598

Date Prepared: Jan. 25. 2024

1. Owner's Identification:

Applicant Name: ANHUI INTCO MEDICAL PRODUCTS CO., LTD.

Location: No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, China

Contact Person: Max Li

Tel: +86-18918364816

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs

Common Name: Exam Gloves

Classification Name: Non-Powdered Patient Examination Glove Specialty

Regulation: 21 CFR 880.6250

Product Code: LZA, LZC, QDO, OPJ

Classification Panel: General Hospital

Device Class: Class I

3. Predicate Device Information:

Better Care Plastic Technology Co., Ltd.

Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K223713)

Product code LZA, LZC, QDO, OPJ.

4. Device Description:

Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large, Extra Extra Large. Gloves meet the specification of ASTM D6319- 19 and have been tested for resistance to permeation by chemotherapy drugs, Fentanyl Citrate, and select other drugs as per ASTM D6978-05(2019). The gloves are single use, disposable, and provided non-sterile.

5. Indications for Use:

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Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs 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, Fentanyl Citrate, and Select Other Drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Table 1

Chemotherapy Drugs	Minimum Breakthrough Detection Time (minutes)
Bendamustine HCl; 5 mg/ml	>240 min.
Bleomycin sulfate; 15 mg/ml	>240 min.
Busulfan; 6 mg/ml	>240 min.
Carboplatin; 10 mg/ml	>240 min.
Carfilzomib; 2 mg/ml	>240 min.
Carmustine; 3.3 mg/ml	1.7
Cetuximab; 2 mg/ml	>240 min.
Cisplatin; 1 mg/ml	>240 min.
Cladribine; 1 mg/ml	>240 min.
Cyclophosphamide; 20 mg/ml	>240 min.
Cytarabine (Cytosine); 100 mg/ml	>240 min.
Cytovene (Ganciclovir); 10 mg/ml	>240 min.
Dacarbazine; 10 mg/ml	>240 min.
Daunorubicin HCL; 5 mg/ml	>240 min.
Decitabine; 5 mg/ml	>240 min.
Docetaxel; 20 mg/ml	>240 min.
Doxorubicin HCl; 2 mg/ml	>240 min.
Epirubicin HCl; 2 mg/ml	>240 min.
Etoposide; 20 mg/ml	>240 min.
Fludarabine Phosphate; 25 mg/ml	>240 min.
Fluorouracil; 50 mg/ml	>240 min.
Fulvestrant; 50 mg/ml	>240 min.
Gemcitabine HCl; 38 mg/ml	>240 min.
Idarubicin HCl; 1 mg/ml	>240 min.
Ifosfamide; 50 mg/ml	>240 min.
Irinotecan HCl; 20 mg/ml	>240 min.
Mechlorethamine HCL; 1 mg/ml	>240 min.
Melphalan HCl; 5 mg/ml	>240 min.
Methotrexate; 25 mg/ml	>240 min.
Mitomycin C; 0.5 mg/ml	>240 min.
Mitoxantrone HCl; 2 mg/ml	>240 min.
Oxaliplatin; 5 mg/ml	>240 min.
Pacilitaxel; 6 mg/ml	>240 min.
Pemetrexed; 25 mg/ml	>240 min.
Rituximab; 10 mg/ml	>240 min.
Thio Tapa; 10 mg/ml	0

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Topotecan HCl; 1 mg/ml	>240 min.
Trisenox (Arsenic Trioxide); 1 mg/ml	>240 min.
Velcade (Bortezomib); 1 mg/ml	>240 min.
Vidaza (Azacytidine); 25mg/ml	>240 min.
Vincristine Sulfate; 1 mg/ml	>240 min.
Vinorelbine Tartrate; 10 mg/ml	>240 min.
Zoledronic Acid; 0.8 mg/ml	>240 min.

*Please note that the following drugs have extremely low permeation times:

Carmustine: 1.7 minutes, Thio Tepa: 0 minutes

Warning: Do not use with Carmustine and Thio Tepa.

Fentanyl Citrate & Other Drugs	Minimum Breakthrough Detection Time (minutes)
Fentanyl Citrate Injection(100 mcg/2ml)	>240 min.
Chloroquine; 50mg/ml	>240 min.
Cyclosporin A; 100mg/ml	>240 min.
Retrovir; 10 mg/ml	>240 min.

6. Comparison of Subject Device and Predicate Device:

The following tables are summaries of the technological characteristics, biocompatibility and performance testing of the proposed and predicate devices. General Comparison Table:

Device	Proposed Device	Predicate Device	Comparison
510K #	K233598	K223713	-
Product Name	Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs	Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	-
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	Powder Free Nitrile Examination Glove 2.8 Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs 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, Fentanyl Citrate, and Select Other Drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate.	Same

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	Medical Gloves to Permeation by Chemotherapy Drugs.		
Powder free	Yes	Yes	Same
Design feature	Ambidextrous	Ambidextrous	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Grey	Different
Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL	Different
Sterile	Non-Sterile	Non-Sterile	Same
Use	Singe use	Single use	Same
Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs Claim	See below comparison table	See below comparison table	Similar

Analysis: The proposed device has size XS, S, M, L, XL, XXL and Blue color, while the predicate device has size XS, S, M, L, XL and Grey 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 does not raise any new safety or performance questions.

Technological Characteristic and Biocompatibility Comparison Table:

Item	Standard	Proposed device	Predicate device K223713	Result
Dimension	ASTM D6319-19	Minimum 220mm for size XS and S, 230mm for size M, L, XL Width(mm): XS: 70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10 XXL: 130±10 Thickness(mm): Palm: Minimum 0.05 Finger: Minimum 0.05	Length: Min 230mm Width(mm): XS: 70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10 XXL: / Thickness:(mm) Palm: Minimum 0.05 Finger: Minimum 0.05	Similar
Physical properties Before aging Tensile strength Ultimate elongation	ASTM D6319-19 ASTM D412-16	14MPa, min 500%, min	14MPa, min 500%, min	Same
After aging Tensile strength Ultimate elongation		14MPa, min 400%, min	14MPa, min 400%, min	Same

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Freedom from holes	ASTM D6319-19 ASTM D5151-19	G-I, AQL2.5	G-I, AQL2.5	Same
Residual Powder	ASTM D6319-19 ASTM D6124-06	≤ 2 mg per glove	≤ 2 mg per glove	Same
Biocompatibility	Irritation ISO 10993-23	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.	Based on the criteria, the test article extracts were considered negligible irritants.	Similar ^①
	Sensitization ISO 10993-10	The sample extract elicits no sensitization reactions under the test conditions	Based on the criteria and conditions of the study, the test article is classified as a non-sensitizer	Similar
	Acute Systemic Toxicity Test ISO 10993 -11	No death or systemic toxicity was observed in the mice which received injection of the extract	Based on the criteria, the test article meets the requirements	Similar

① The new version of standard for Skin Irritation we refer is ISO 10993-23:2021, the test method and process is the same as the old version ISO 10993-10

Chemotherapy Permeation, Fentanyl Citrate, and Select Other Drugs Comparison Claim:

Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs	Minimum BDT (Minutes)		Remark
	Proposed device	Predicate device K223713	
Bendamustine HCl ; 5 mg/ml	>240 min.	>240 min.	Same
Bleomycin sulfate ; 15 mg/ml	>240 min.	>240 min.	Same
Busulfan ; 6 mg/ml	>240 min.	>240 min.	Same
Carboplatin; 10 mg/ml	>240 min.	>240 min.	Same
Carfilzomib ; 2 mg/ml	>240 min.	>240 min.	Same
Carmustine ; 3.3 mg/ml	1.7	13.9	Different*
Cetuximab ; 2 mg/ml	>240 min.	>240 min.	Same
Chloroquine ; 50mg/ml	>240 min.	--	Different*
Cisplatin ; 1 mg/ml	>240 min.	>240 min.	Same
Cladribine ; 1 mg/ml	>240 min.	--	Different*
Cyclophosphamide; 20 mg/ml	>240 min.	>240 min.	Same
Cyclosporin A; 100mg/ml	>240 min.	--	Different*
Cytarabine (Cytosine) ; 100 mg/ml	>240 min.	>240 min.	Same
Cytovene (Ganciclovir); 10 mg/ml	>240 min.	>240 min.	Same
Dacarbazine ; 10 mg/ml	>240 min.	>240 min.	Same
Daunorubicin HCL; 5 mg/ml	>240 min.	>240 min.	Same
Decitabine ; 5 mg/ml	>240 min.	>240 min.	Same
Docetaxel ; 20 mg/ml	>240 min.	>240 min.	Same

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Doxorubicin HCL ; 2 mg/ml	>240 min.	>240 min.	Same
Epirubicin HCL ; 2 mg/ml	>240 min.	>240 min.	Same
Etoposide ; 20 mg/ml	>240 min.	>240 min.	Same
Eribulin Mesylate; 0.5 mg/ml	--	>240 min.	Different*
Fludarabine Phosphate; 25 mg/ml	>240 min.	>240 min.	Same
Fluorouracil ; 50 mg/ml	>240 min.	>240 min.	Same
Fulvestrant ; 50 mg/ml	>240 min.	>240 min.	Same
Gemcitabine HCl ; 38 mg/ml	>240 min.	>240 min.	Same
Idarubicin HCl ; 1 mg/ml	>240 min.	>240 min.	Same
Ifosfamide ; 50 mg/ml	>240 min.	>240 min.	Same
Irinotecan HCl ; 20 mg/ml	>240 min.	>240 min.	Same
Mechlorethamine HCL; 1 mg/ml	>240 min.	>240 min.	Same
Melphalan HCl; 5 mg/ml	>240 min.	>240 min.	Same
Methotrexate ; 25 mg/ml	>240 min.	>240 min.	Same
Mitomycin C ; 0.5 mg/ml	>240 min.	>240 min.	Same
Mitoxantrone HCl ; 2 mg/ml	>240 min.	>240 min.	Same
Oxaliplatin ;5 mg/ml	>240 min.	>240 min.	Same
Pacilitaxel ; 6 mg/ml	>240 min.	>240 min.	Same
Pemetrexed ; 25 mg/ml	>240 min.	>240 min.	Same
Pertuzumab; 30 mg/ml	--	>240 min.	Different*
Raltitrexed monohydrate	--	>240 min.	Different*
Retrovir ; 10 mg/ml	>240 min.	>240 min.	Same
Rituximab ; 10 mg/ml	>240 min.	>240 min.	Same
Temsirolimus ; 25mg/ml	--	>240 min.	Different*
ThioTEPA ; 10 mg/ml	0	44.4	Different*
Topotecan HCL ; 1 mg/ml	>240 min.	>240 min.	Same
Trastuzumab ; 21mg/ml	--	>240 min.	Different*
Trisenox (Arsenic Trioxide); 1 mg/ml	>240 min.	>240 min.	Same
Velcade (Bortezomib); 1 mg/ml	>240 min.	>240 min.	Same
Vidaza (Azacytidine); 25mg/ml	>240 min.	>240 min.	Same
Vinblastine ; 1mg/ml	--	>240 min.	Different*
Vincristine Sulfate ; 1 mg/ml	>240 min.	>240 min.	Same
Vinorelbine Tartrate; 10 mg/ml	>240 min.	>240 min.	Same
Zoledronic Acid ; 0.8 mg/ml	>240 min.	>240 min.	Same
Fentanyl; 100mcg/2ml	>240 min.	>240 min.	Same
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution	--	>240 min.	Different*

* Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this difference does not raise questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Data

Anhui Intco Medical Products Co.,Ltd.

No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province, China

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Non-clinical tests were conducted to verify that the proposed device met all design specifications.

The test results demonstrated that the proposed device met the performance criteria with the following standards:

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for size XS and S, 230mm for size M, L, XL	Pass
ASTM D6319- 19	Physical Dimensions Palm Width	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL: 120±10mm XXL: 130±10mm	Pass
ASTM D6319- 19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412- 16 (2021)	Physical Properties	Before aging: 14MPa, min 500%, min After aging: 14MPa, min 400%, min	Pass
ASTM D6319- 19 ASTM D5151- 19	Water leak test	G-I, AQL 2.5 (ISO 2859- 1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	Permeation by Chemotherapy Drugs and Fentanyl Citrate	Refer the above table 1	Pass
ISO 10993-10:2021	Skin Sensitization	No Skin sensitization	The sample extract elicits no sensitization reactions under the test conditions
ISO 10993-23:2021	Irritation	No Skin irritation	Under the conditions of this study, the irritation response category of the test

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			article is classified as Negligible for polar extract and Negligible for non-polar extract.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	No death or acute systemic toxicity was observed in the mice which received injection of the extract

- . 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 D412- 16 (2021) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- . ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.
- . ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- . ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation.
- . ISO 10993- 11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

8. Summary of Clinical Testing:

Not provided for the subject device.

9. Conclusion:

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, K223713, Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.