April 1, 2024

Shandong Xingyu Gloves Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K233990
Trade/Device Name: Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000)
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: March 11, 2024
Received: March 11, 2024

Dear Ivy 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)*
K233990

Device Name
Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000)

Indications for Use *(Describe)*
The Nitrile Disposable Examination Glove, Tested for Use with Chemotherapy Drugs and Fentanyl 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.
Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05.
The tested chemotherapy drugs are:
Chemotherapy drug Concentration Minimum Breakthrough Detection Time
Bleomycin sulfate (15.0 mg/ml 15,000 ppm) >240 min
Carboplatin (10.0 mg/ml 10,000 ppm) >240 min
Carmustine (BCNU) (3.3mg/mL 3,300 ppm) 13.2
Cisplatin (1.0 mg/mL 1,000 ppm) >240 min
Cyclophosphamide (20.0 mg/mL 20,000 ppm) >240 min
Cytarabine (Cytosine) (100.0 mg/mL 100,000 ppm) >240 min
Dacarbazine (10.0 mg/mL 10,000 ppm) >240 min
Doxorubicin HCL (2.0 mg/mL 2,000 ppm) >240 min
Etoposide (Toposar) (20.0 mg/mL 20,000 ppm) >240 min
Fluorouracil (5 Flu) (50.0 mg/mL 50,000 ppm) >240 min
Idarubicin (1.0 mg/ml 1,000 ppm) >240 min
Ifosfamide (50.0 mg/mL 50,000 ppm) >240 min
Mechlorethamine HCL (1.0 mg/ml 1,000 ppm) >240 min
Methotrexate (25.0 mg/mL 25,000 ppm) >240 min
Mitomycin C (0.5 mg/mL 500 ppm) >240 min
Mitoxantrone HCL (2.0 mg/mL 2,000 ppm >240 min
Paclitaxel (6.0 mg/mL 6,000 ppm) >240 min
Thiotepa (10.0 mg/mL 10,000 ppm) 13.1
Vincristine Sulfate (1.0 mg/mL 1,000 ppm >240 min

The tested non-chemotherapy drugs are:
Fentanyl Citrate Injection (100 mcg/2mL) >240 min
MESNA (100.0 mg/mL 100,000 ppm) >240 min
Trisenox (1.0 mg/ml 1,000 ppm) >240 min
Note: Carmustine and Thiotepa have extremely low permeation times of 13.2 and 13.1 minutes respectively.
Warning: Do Not Use with Carmustine, 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.

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510(K) Summary

K233990

(As required by 21 CFR 807.92)

Date prepared: 2024-04-01

A. Applicant:

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B. Device:

Trade Name: Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl
Common Name: Nitrile Patient Examination Gloves (Powder Free)
Model: D5000
Size(s): XS, S, M, L, XL, XXL

Regulatory Information
Classification Name: Polymer Patient Examination Glove
Classification: Class I
Product code: LZA (Primary), LZC, OPJ, QDO
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device:

510K Number: K223903
Trade Name: Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl
Manufacturer: SEMPERIT INVESTMENTS ASIA PTE. LTD.
Reference Device

510K Number: K212735
Trade Name: Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)
Manufacturer: Xingyu Medical Tech Co., Ltd.

D. Indications for use of the device:

The Nitrile Disposable Examination Glove, Tested for Use with Chemotherapy Drugs and Fentanyl 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.

Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05.

The tested chemotherapy drugs are:

Chemotherapy drug	Concentration	Minimum Breakthrough Detection Time
Bleomycin sulfate	(15.0 mg/ml 15,000 ppm)	＞240 min
Carboplatin	(10.0 mg/ml 10,000 ppm)	＞240 min
Carmustine (BCNU)	(3.3mg/mL 3,300 ppm)	13.2
Cisplatin	(1.0 mg/mL 1,000 ppm)	＞240 min
Cyclophosphamide	(20.0 mg/mL 20,000 ppm)	＞240 min
Cytarabine (Cytosine)	(100.0 mg/mL 100,000 ppm)	＞240 min
Dacarbazine	(10.0 mg/mL 10,000 ppm)	＞240 min
Doxorubicin HCL	(2.0 mg/mL 2,000 ppm)	＞240 min
Etoposide (Toposar)	(20.0 mg/mL 20,000 ppm)	＞240 min
Fluorouracil (5 Flu)	(50.0 mg/mL 50,000 ppm)	＞240 min
Idarubicin	(1.0 mg/ml 1,000 ppm)	＞240 min
Ifosfamide	(50.0 mg/mL 50,000 ppm)	＞240 min
Mechlorethamine HCL	(1.0 mg/ml 1,000 ppm)	＞240 min
Methotrexate	(25.0 mg/mL 25,000 ppm)	＞240 min
Mitomycin C	(0.5 mg/mL 500 ppm)	＞240 min
Mitoxantrone HCL	(2.0 mg/mL 2,000 ppm	＞240 min
Paclitaxel	(6.0 mg/mL 6,000 ppm)	＞240 min
Thiotepa	(10.0 mg/mL 10,000 ppm)	13.1
Vincristine Sulfate	(1.0 mg/mL 1,000 ppm	＞240 min

The tested non-chemotherapy drugs are:

Fentanyl Citrate Injection	(100 mcg/2mL)	＞240 min
MESNA	(100.0 mg/mL 100,000 ppm)	＞240 min
Trisenox	(1.0 mg/ml 1,000 ppm)	＞240 min

Note: Carmustine and Thiotepa have extremely low permeation times of 13.2 and 13.1 minutes respectively.

Warning: Do Not Use with Carmustine, Thiotepa

E. Device Description:

The Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000) are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are blue color, powder free, nitrile ambidextrous gloves. The gloves are offered in six sizes, extra small, small, medium, large, extra-large and extra extra-large, packed in a paper box.

The gloves are designed and manufactured in accordance with the ASTM D6319 standard and are tested for use with chemotherapy drugs and Fentanyl per ASTM D6978 standard.

F. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	K233990	K223903	-
Product Name	Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000)	Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl	-
Product Code	LZA (primary), LZC, OPJ, QDO	LZA (primary), LZC, OPJ, QDO	Same
Classification	Class I	Class I	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	The Nitrile Disposable Examination Glove, Tested for Use with Chemotherapy Drugs and Fentanyl 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 using ASTM D6978. The tested chemotherapy drugs are: Chemotherapy drug Concentration Minimum Breakthrough Detection Time Bleomycin sulfate (15.0 mg/ml 15,000 ppm) ＞240 min Carboplatin (10.0 mg/ml 10,000 ppm)＞240 min Carmustine (BCNU) (3.3mg/mL 3,300 ppm) 13.2 Cisplatin (1.0 mg/mL 1,000 ppm) ＞240 min Cyclophosphamide (20.0 mg/mL 20,000 ppm) ＞240 min Cytarabine (Cytosine) (100.0 mg/mL 100,000 ppm) ＞240 min Dacarbazine (10.0 mg/mL 10,000 ppm) ＞240 min Doxorubicin HCL (2.0 mg/mL 2,000	This device is an ambidextrous patient examination glove that is a non-sterile, single use, disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between patient and examiner. The tested chemotherapy drugs are: Carmustine (BCNU) (3.3 mg/ml). Permeation time: Carmustine (BCNU) has extremely low permeation times of 14.7 minutes. Cisplatin (1.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Cyclophosphamide (Cytoxan) (20.0 mg/ ml). Permeation time: no breakthrough up to 240 minutes Cytarabine (100 mg/ml). Permeation time: no breakthrough up to 240 minutes Dacarbazine (DTIC) (10.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Doxorubicin Hydrochloride (2.0 mg/ml). Permeation time: no breakthrough up	Similar The proposed device and the predicate device have same indications, only minor differences on different drugs and the penetration time of carmustine and thiotepa between the proposed device and the predicate device, which will not raise any new safety or performance

	ppm) ＞240 min Etoposide (Toposar) (20.0 mg/mL 20,000 ppm) ＞240 min Fluorouracil (5 Flu) (50.0 mg/mL 50,000 ppm) ＞240 min Idarubicin (1.0 mg/ml 1,000 ppm) ＞240 min Ifosfamide (50.0 mg/mL 50,000 ppm) ＞240 min Mechlorethamine HCL (1.0 mg/ml 1,000 ppm) ＞240 min MESNA (100.0 mg/mL 100,000 ppm) ＞240 min Methotrexate (25.0 mg/mL 25,000 ppm) ＞240 min Mitomycin C (0.5 mg/mL 500 ppm) ＞240 min Mitoxantrone HCL (2.0 mg/mL 2,000 ppm ＞240 min Paclitaxel (6.0 mg/mL 6,000 ppm) ＞240 min Thiotepa (10.0 mg/mL 10,000 ppm) 13.1 Trisenox (1.0 mg/ml 1,000 ppm) ＞240 min Vincristine Sulfate (1.0 mg/mL 1,000 ppm ＞240 min Fentanyl Citrate Injection (100 mcg/2mL)＞240 min Note: Carmustine and Thiotepa have extremely low permeation times of 13.2 and 13.1 minutes respectively. Warning: Do Not Use with Carmustine, Thiotepa	to 240 minutes Etoposide (20.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Fluorouracil (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Ifosfamide (50.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Methotrexate (25.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitomycin C (0.5 mg/ml). Permeation time: no breakthrough up to 240 minutes Mitoxantrone (2.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Paclitaxel (Taxol) (6.0 mg/ml). Permeation time: no breakthrough up to 240 minutes Thiotepa (10.0 mg/ml). Permeation time: Thiotepa has extremely low permeation times of 13.6 minutes Vincristine Sulfate (1.0 mg/ml). Permeation time: no Breakthrough up to 240 minutes. The tested Opiod is: Fentanyl Citrate Injection (100mcg/2mL). Permeation: no breakthrough up to 240 minutes Please note that the following drugs have extremely low permeation times: Carmustine: 14.7 minutes Thiotepa: 13.6 minutes Warning: DO NOT USE WITH CARMUSTINE OR THIOTEPA	concerns.
Powder free	Yes	Yes	Same
Design feature	Ambidextrous	Ambidextrous	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same

Use	Singe use	Single use	Same
Labeling claim	Tested for Use with Chemotherapy Drugs and Fentanyl	Tested for Use with Chemotherapy Drugs and Fentanyl	Same

Table 2 Device dimension comparison

Technological characteristics	**Proposed Device (K233990)**	**Predicate Device (K223903)**	**Result**
Length			
XS, S	Minimum 240mm	Minimum 220mm	Different The length dimension of the proposed device is not the same with the predicate device, while both are meet the criteria of the ASTM D6319 standard.
M, L, XL		Minimum 230mm	
XXL		Not available	
Palm width (size) (mm)			
XS	70±10	70±10	Same
S	80±10	80±10	Same
M	95±10	95±10	Same
L	110±10	110±10	same
XL	120±10	120±10	Same
XXL	130±10	Not available	Different The proposed device has one more size (XXL) than the predicate device, however the dimension of the proposed device has been tested and complied with the ASTM D6319-19. This dimension different will not raise any new safety or performance concerns.
Thickness (mm)			
Finger	⩾0.05	⩾0.05	Same
Palm	⩾0.05	⩾0.05	Same

Table 3 Performance comparison

Item			**Proposed device (K233990)**	**Predicate device (K223903)**	**Result**
Physical properties	Before aging	Tensile strength	14MPa, min	14MPa, min	Same
		Ultimate elongation	500%, min	500%, min	Same
	After aging	Tensile strength	14MPa, min	14MPa, min	Same

		Ultimate elongation	400%, min	400%, min	Same
	Comply with ASTM D6319			Comply with ASTM D6319	Same
Freedom from holes		Be free from holes when tested in accordance with ASTM D5151 G-1, AQL 2.5		Be free from holes when tested in accordance with ASTM D5151 G-1, AQL 2.5	Same
Residual Powder		Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124	Same

Table 4 Chemotherapy Permeation and Fentanyl Citrate Comparison Claim:

Tested Chemotherapy Drugs, non-chemotherapy drugs and fentanyl and Concentration	**Minimum breakthrough detection time in minutes**			**Result**
	Proposed device (K233990)	**Predicate device (K223903)**	**Reference device (K212735**	
Bleomycin sulfate (15.0 mg/ml 15,000 ppm)	＞240	Not available	＞240	Same with reference device
Carboplatin (10.0 mg/ml 10,000 ppm)	＞240	Not available	＞240	Same with reference device
Carmustine (BCNU) (3.3mg/mL 3,300 ppm)	13.2	14.7	47.9	Similar
Cisplatin (1.0 mg/mL 1,000 ppm)	＞240	＞240	＞240	Same
Cyclophosphamide (20 mg/mL 20,000 ppm)	＞240	＞240	＞240	Same
Cytarabine (Cytosine) (100 mg/mL 100,000 ppm)	＞240	＞240	＞240	Same
Dacarbazine (10 mg/mL 10,000 ppm)	＞240	＞240	＞240	Same
Doxorubicin HCL (2.0 mg/mL 2,000 ppm)	＞240	＞240	＞240	Same
Etoposide (Toposar) (20.0 mg/mL 20,000 ppm)	＞240	＞240	＞240	Same
Fluorouracil (5 Flu) (50.0 mg/mL 50,000 ppm)	＞240	＞240	＞240	Same
Idarubicin (1.0 mg/ml 1,000 ppm)	＞240	Not available	＞240	Same with reference device
Ifosfamide (50.0 mg/mL 50,000 ppm)	＞240	＞240	＞240	Same
Mechlorethamine HCL	＞240	Not available	＞240	Same with

(1.0 mg/ml 1,000 ppm)				reference device
MESNA (100.0 mg/mL 100,000 ppm)	＞240	Not available	＞240	Same with reference device
Methotrexate (25.0 mg/mL 25,000 ppm)	＞240	＞240	＞240	Same
Mitomycin C (0.5 mg/mL 500 ppm)	＞240	＞240	＞240	Same
Mitoxantrone HCL (2.0 mg/mL 2,000 ppm	＞240	＞240	＞240	Same
Paclitaxel (6.0 mg/mL 6,000 ppm)	＞240	＞240	＞240	Same
Thiotepa (10.0 mg/mL 10,000 ppm)	13.1	13.6	＞240	Similar
Trisenox (1.0 mg/ml 1,000 ppm)	＞240	Not available	＞240	Same with reference device
Vincristine Sulfate (1.0 mg/mL 1,000 ppm	＞240	＞240	＞240	Same
Fentanyl Citrate Injection (100 mcg/2mL)	＞240	＞240	Not applicable	Same

Similar Analysis:

Minor differences on the penetration time of carmustine and thiotepa between the proposed device and the predicate device, which will not raise any new safety or performance concerns.

Table 5 Biocompatibility comparison

Item		**Proposed device (K233990)**	**Predicate device (K223903)**	**Result**
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation ISO 10993-23	Under the conditions of the study, not an irritant.	Comply with ISO 10993-10	Same
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer.		
	Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, the device extract does not induce acute	Not available	Different Acute systemic toxicity information for the predicate device is not publicly

		systemic toxicity response.		available. This does not raise different safety or performance questions since the subject device has acceptable biocompatibility per the biocompatibility endpoint assessment.

G. Summary of Non-Clinical Testing

- **Biocompatibility**

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the subject device is Surface and External Communicating Device category and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to evaluate the biocompatibility of Nitrile Disposable Examination Gloves as per *Guidance for Industry and FDA Staff -Medical Glove Guidance Manual issued on January 22, 2008*:

- ISO 10993-23: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Acute Systemic Toxicity

- **Performance Testing**

Physical performance testing of the proposed device was conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application* and are tested for use with chemotherapy drugs and Fentanyl per ASTM D6978 standard.

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 for Medical Application
- ASTM D6124-06 (2022) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Test Method	Purpose	Acceptance Criteria	Results
Dimensions (width) (thickness) ASTM D6319-19	The purpose of the test is to evaluate the physical dimension of the glove	Length 240mm min	Pass
		Width XS: 70±10mm S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm	Pass

		XXL: 130±10mm	
		Palm - 0.05mm min. Finger - 0.05mm min.	Pass
Physical properties ASTM D6319-19	The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging	Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Pass
Freedom from holes ASTM D5151-19	The purpose of the test is to detect holes in the gloves	No leakage at sampling level of G-1, AQL 2.5	Pass
Residual Powder ASTM D6124-06 (2022)	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass
Permeation by Chemotherapy Drugs ASTM D6978-05 (2019)	The purpose of the test is to detect the Permeation time by Chemotherapy Drugs of the glove	Refer the above table 4	Pass

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 Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl (D5000) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K223903.