



January 12, 2024

Anhui Powerguard Technology Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K233520

Trade/Device Name: Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with
Chemotherapy Drugs and Fentanyl
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: November 1, 2023
Received: November 1, 2023

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

Indications for Use

510(k) Number (if known)

K233520

Device Name

Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl

Indications for Use (Describe)

The Powder free, Non-sterile, Blue Nitrile Examination Gloves, 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.

The tested chemotherapy drugs are:

Chemotherapy drug Concentration Minimum Breakthrough Detection Time

Carmustine (3.3mg/mL 3,300 ppm) 11.1 min

Cisplatin (1.0 mg/mL 1,000 ppm) >240 min

Cyclophosphamide (20 mg/mL 20,000 ppm) >240 min

Cytarabine (Cytosine) (100 mg/mL 100,000 ppm) >240 min

Dacarbazine (10 mg/mL 10,000 ppm) >240 min

Doxorubicin (Adriamycin) (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

Ifosfamide (50.0 mg/mL 50,000 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) 34.8 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 11.1 and 34.8 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

K233520

(As required by 21 CFR 807.92)

Date prepared: 2024-01-12

A. Applicant:

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B. Device:

Trade Name: Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl

Common Name: Nitrile Patient Examination Gloves (Powder Free)

Size(s): XS, S, M, L, XL

Regulatory Information

Classification Name: Polymer Patient Examination Glove

Classification: Class I

Product code: LZA, LZC, OPJ, QDO

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

C. Predicate device:

K223903

Non-Sterile, Single use, Powder-free examination glove, Blue, tested for use with Chemotherapy drugs and Fentanyl

SEMPERIT INVESTMENTS ASIA PTE. LTD.

D. Indications for use of the device:

The Powder free, Non-sterile, Blue Nitrile Examination Gloves, 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.

The tested chemotherapy drugs are:

Chemotherapy drug	Concentration	Minimum Breakthrough Detection Time
Carmustine	(3.3mg/mL 3,300 ppm)	11.1 min
Cisplatin	(1.0 mg/mL 1,000 ppm)	> 240 min
Cyclophosphamide	(20 mg/mL 20,000 ppm)	> 240 min
Cytarabine (Cytosine)	(100 mg/mL 100,000 ppm)	> 240 min
Dacarbazine	(10 mg/mL 10,000 ppm)	> 240 min
Doxorubicin (Adriamycin)	(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
Ifosfamide	(50.0 mg/mL 50,000 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)	34.8 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 11.1 and 34.8 minutes respectively.

Warning: Do Not Use with Carmustine, Thiotepa

E. Device Description:

The Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl 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 five sizes, extra small, small, medium, large, and 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
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510K #		K223903	-
Product Name	Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl	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 Powder free, Non-sterile, Blue Nitrile 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. The tested chemotherapy drugs are: Chemotherapy drug Concentration Minimum Breakthrough Detection Time Carmustine (3.3mg/mL 3,300 ppm) 11.1 Cisplatin (1.0 mg/mL 1,000 ppm) > 240 min Cyclophosphamide (20 mg/mL 20,000 ppm) > 240 min Cytarabine (Cytosine) (100 mg/mL 100,000 ppm) > 240 min Dacarbazine (10 mg/mL 10,000 ppm) > 240 min Doxorubicin (Adriamycin) (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 Ifosfamide (50.0 mg/mL 50,000 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) 34.8	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 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	Similar

	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 11.1 and 34.8 minutes respectively. Warning: Do Not Use with Carmustine, Thiotepa	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 Opioid 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	
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

Analysis: The proposed device and the predicate device have same indications, only 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 2 Device dimension comparison

Technological characteristics	Proposed Device	Predicate Device (K223903)	Result
Length			
XS, S	Minimum 220mm	Minimum 220mm	Same

M, L, XL	Minimum 230mm	Minimum 230mm	Same
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
Thickness (mm)			
Finger	≥0.05	≥0.05	Same
Palm	≥0.05	≥0.05	Same

Table 3 Performance comparison

Item			Proposed device	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 Drug and Concentration	Minimum breakthrough detection time in minutes		Result
	Proposed device	Predicate device (K223903)	
Carmustine (3.3mg/mL 3,300 ppm)	11.1	14.7	Similar
Cisplatin (1.0 mg/mL 1,000 ppm)	> 240	> 240	Same
Cyclophosphamide (20 mg/mL 20,000 ppm)	> 240	> 240	Same
Cytarabine (Cytosine) (100 mg/mL 100,000 ppm)	> 240	> 240	Same
Dacarbazine (10 mg/mL 10,000 ppm)	> 240	> 240	Same
Doxorubicin (Adriamycin) (2.0 mg/mL 2,000 ppm)	> 240	> 240	Same
Etoposide (Toposar) (20.0 mg/mL 20,000 ppm)	> 240	> 240	Same

Fluorouracil (5 Flu) mg/mL 50,000 ppm)	(50.0	> 240	> 240	Same
Ifosfamide (50.0 mg/mL 50,000 ppm)	mg/mL	> 240	> 240	Same
Methotrexate (25.0 mg/mL 25,000 ppm)	mg/mL	> 240	> 240	Same
Mitomycin C (0.5 mg/mL 500 ppm)	mg/mL	> 240	> 240	Same
Mitoxantrone HCL (2.0 mg/mL 2,000 ppm)	mg/mL	> 240	> 240	Same
Paclitaxel (6.0 mg/mL 6,000 ppm)	mg/mL	> 240	> 240	Same
Thiotepa (10.0 mg/mL 10,000 ppm)	mg/mL	34.8	13.6	Similar
Vincristine Sulfate (1.0 mg/mL 1,000 ppm)		> 240	> 240	Same
Fentanyl Citrate Injection (100 mcg/2mL)		> 240	> 240	Same

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	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.		
	In Vitro Cytotoxicity ISO 10993-5	Under the conditions of the study, the test article extract showed potential toxicity.	Not available	Different
	Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, the device extract does not	Not available	Different

		induce acute systemic toxicity response.		
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Analysis: In vitro cytotoxicity and acute systemic toxicity information for the predicate device is not publicly 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 Device category, Skin Contact and duration of contact is Limited (≤ 24 h). The following tests for the subject device were conducted to evaluate the biocompatibility:

- ISO 10993-5: In Vitro Cytotoxicity
- 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 (Reapproved 2017) 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 220mm min for XS, S 230mm min for M, L, XL	Pass
		Width XS: 70±10mm S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm	Pass
		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:	Pass

		Before Aging 500%, min. After Aging 400%, min.	
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(Reapproved 2017)	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 and Fentanyl of the glove	Refer the above table 4	Pass

H. Summary of Clinical Testing

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Powder free, Non-sterile, Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K223903.