January 15, 2025

Sunray Medical Products Inc.
Youyou Zheng
General Manager
3973 Schaefer Ave.
Chino, California 91710

Re: K242936
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue, Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
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: December 20, 2024
Received: December 20, 2024

Dear Youyou Zheng:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242936

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

Indications for Use *(Describe)*
The 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.
The glove was tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2023)

The following chemicals have been tested with these gloves:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes	
	Blue	Black
Carmustine 3.3 mg/ml (3,300 ppm)	14.7, Do not use	22.6, Do not use
Cisplatin 1mg/ml (1,000 ppm)	>240	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240
Methotrexate, 25mg/ml (25,000ppm)	>240	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240
Thiotepa, 10mg/ml (10,000ppm)	36.4, Do not use	35.6, Do not use

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes	
	Blue	Black
Fentanyl Citrate Injection, 100mcg/2mg	>240	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 14.7 minutes, Thio Tepa: 36.4 minutes (Blue);
Carmustine: 22.6 minutes, Thio Tepa: 35.6 minutes (Black);
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number: K242936

1. Submitter's Information:

Name: Sunray Medical Products Inc.
Address: 3973 Schaefer Ave. Chino, California, 91710, United States
Contact: Ms Youyou Zheng / General Manager
Tel: 909 590 1611
Email: fdareg@sunraymedicalinc.com
Date Prepared: December 18, 2024

2. Device Identification:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Blue, Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name: Patient Examination Gloves
Classification Name: Non-powdered Patient Examination Glove
Regulation Number: 21 CFR 880.6250
Product Code: LZA LZC QDO OPJ
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Genabio Diagnostics Inc.
GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS/S/M/L/XL)
510(k) Number: K240545

4. Device Description:

The subject device is single use, disposable and non-sterile gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder free, ambidextrous with beaded cuff, Blue/Black colored, nitrile, and tested for use with chemotherapy drugs and Fentanyl Citrate. The gloves are offered in six sizes: XS, S, M, L, XL, XXL.

5. Indications for Use:

The 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.
The glove was tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2023).

Tested chemotherapy drugs and Fentanyl Citrate are as follows:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)	
	Blue	Black
Carmustine, 3.3 mg/ml (3,300 ppm)	14.7, Do not use	22.6, Do not use
Cisplatin 1mg/ml (1,000 ppm)	>240	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240
Methotrexate, 25mg/ml (25,000ppm)	>240	>240

Paclitaxel, 6mg/ml (6,000ppm)	>240	>240
Thiotepa, 10mg/ml (10,000ppm)	36.4, Do not use	35.6, Do not use

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time (Minutes)	
	Blue	Black
Fentanyl Citrate Injection, 100mcg/2ml	>240	>240

*Please note that the following drugs have low permeation times:
Carmustine: 14.7 minutes, Thiotepa: 36.4 minutes (Blue);
Carmustine: 22.6 minutes, Thiotepa: 35.6 minutes (Black)
Warning: Do not use with Carmustine and Thiotepa.

6. Comparison of Subject Device and Predicate Device:

General Comparison Table

Items	Subject Device K242936	Predicate Device K240545	Comparison Result
Product Code	LZA, LZC, QDO,OPJ	LZA, LZC, QDO,OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Sterility	Non-sterile	Non-sterile	Same
Shelf Life	3 years	/	Different*
Material	Nitrile	Nitrile	Same
Available Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL	Different**
Rx or OTC	OTC	OTC	Same
Indications for Use	The 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. The glove was tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2023).	The GenaCheck™ Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. 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.	Same
Powdered or Powder free	Powder free	Powder free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue, Black	Purple	Different***
Labeling Information	Single-use, powder free, device color, device name, glove size and quantity, Non-Sterile, Expiration date, a statement of standard ASTM D6978 compliance and a summary of the testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978 compliance and a summary of the testing results.	Similar*
Chemotherapy Drugs and Fentanyl Citrate Claim	See below comparison table	See below comparison table	/

Remarks:
** The subject device has been carried out the shelf life study according to the recognized standard ASTM D7160 and it can support the 3years shelf life of subject device, so the difference does not raise questions of safety and effectiveness.*
*** The subject device has Size XXL and meet the requirements of ASTM D6319. so the difference does not raise questions of safety and effectiveness.*
**** The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table

Technological Characteristics	Subject Device K242936		Predicate Device K240545	Comparison Result
	Blue	Black		
Length (mm) (Minimum)	Minimum 220 mm (Sizes XS-S) Minimum 230 mm (sizes M–XXL) Meet ASTM D6319	Minimum 220 mm (Sizes XS-S) Minimum 230 mm (sizes M–XXL) Meet ASTM D6319	Minimum 220 mm (Sizes XS-S) Minimum 230 mm (sizes M – XL) Meet ASTM D6319	Similar*
Palm Width (size) (mm)				
XS	70±10	70±10	70±10	Same
S	80±10	80±10	80±10	Same
M	95±10	95±10	95±10	Same
L	110±10	110±10	110±10	Same
XL	120±10	120±10	120±10	Same
XXL	130±10	130±10	/	Different*
Thickness (mm) (Minimum)				
Finger	0.05	0.05	0.05	Same
Palm	0.05	0.05	0.05	Same
Tensile Strength, Before Aging, min	14MPa Meet ASTM D6319	14MPa Meet ASTM D6319	14MPa Meet ASTM D6319	Same
Ultimate Elongation, Before Aging, min	500% Meet ASTM D6319	500% Meet ASTM D6319	500% Meet ASTM D6319	Same
Tensile Strength, After Accelerated Aging, min	14MPa Meet ASTM D6319	14MPa Meet ASTM D6319	14MPa Meet ASTM D6319	Same
Ultimate Elongation, After Accelerated Aging, min	400% Meet ASTM D6319	400% Meet ASTM D6319	400% Meet ASTM D6319	Same
Freedom from holes	G-I, AQL 2.5 Meet ASTM D6319	G-I, AQL 2.5 Meet ASTM D6319	G-I, AQL 2.5 Meet ASTM D6319	Same
Powder residual	≤ 2 mg per glove Meet ASTM D6319	≤ 2 mg per glove Meet ASTM D6319	≤ 2 mg per glove Meet ASTM D6319	Same
In vitro Cytotoxicity ISO 10993-5: 2009	The test article extract showed evidence of causing severe cell lysis or toxicity. Toxicity concerns was addressed by Acute Systemic Toxicity testing.	The test article extract showed evidence of causing severe cell lysis or toxicity. Toxicity concerns was addressed by Acute Systemic Toxicity testing.	Under conditions of the study, device extract is cytotoxic.	Same
Acute Systemic Toxicity Test ISO 10993-11: 2017	There was no mortality or evidence of systemic toxicity from the extracts injected into	There was no mortality or evidence of systemic toxicity from the extracts injected into	Under the conditions of the study, the test article did not show acute systemic toxicity in	Same

	mice. Each test article extract met the requirements of the study.	mice. Each test article extract met the requirements of the study.	vivo.	
Dermal Sensitization ISO 10993-10: 2021	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	Under the conditions of the study, not a sensitizer.	Same
Primary Skin Irritation ISO 10993-23: 2021	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the SC and SO test article extracts, respectively.	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the SC and SO test article extracts, respectively.	Under the conditions of the study, not an irritant.	Same

Remarks:
** The subject device has Size XXL and meet the requirements of ASTM D6319. so the difference does not raise questions of safety and effectiveness.*

Chemotherapy Permeation and Fentanyl Citrate Comparison Table

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (BDT) (Minutes)			Comparison Result
	Subject Device K242936		Predicate Device K240545	
	Blue	Black		
Carmustine, 3.3 mg/ml (3,300 ppm)	14.7	22.6	22.8	Similar*
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	Same
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	Same
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240	Same
Thiotepa, 10mg/ml (10,000ppm)	36.4	35.6	37.9	Similar*
Mitomycin C, 0.5mg/ml (500 ppm)	No Test	No Test	>240	Different**
Vincristine Sulfate, 1mg/ml (1,000 ppm)	No Test	No Test	>240	Different**

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time (BDT) (Minutes)		Comparison Result
	Subject Device K242936	Predicate Device K240545	

	Blue	Black		
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	>240	Same

Remarks:
**The breakthrough detection times of Carmustine and Thiotepa of subject device are similar with that of the predicate device. The Chemotherapy Labeling Claims has clearly defined on the labeling and therefore it does not raise questions of safety and effectiveness.*
*** The information of Mitomycin C and Vincristine sulfate will not be labeled in the labeling, so it does not raise questions of safety and effectiveness.*

7. Summary of Non-Clinical Performance Data

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	Purpose	Acceptance Criteria	Results
ASTM D6319- 19(2023)	To determine the length of the gloves	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	Pass Meet the requirements of ASTM D6319
ASTM D6319- 19(2023)	To determine the Physical Dimensions (Palm Width)	XS: 70 ±10mm S: 80 ±10mm M: 95 ±10mm L:110 ±10mm XL:120 ±10mm XXL:130 ±10mm	Pass Meet the requirements of ASTM D6319
ASTM D6319- 19(2023)	To determine the Physical Dimensions (Thickness)	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass Meet the requirements of ASTM D6319
ASTM D6319- 19(2023) ASTM D412-16(2021)	To determine the Physical Properties	Tensile Strength (Min14 MPa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass Meet the requirements of ASTM D6319
ASTM D6319- 19(2023) ASTM D5151-19(2023)	To determine the Water leak test	AQL 2.5	Pass Meet the requirements of ASTM D6319
ASTM D6319- 19(2023) ASTM D6124-06 (2022)	To determine the Powder Residue	Max 2mg/glove	Pass Meet the requirements of ASTM D6319
ASTM D6978-05 (2023)	chemical permeation testing	/	Refer to the above table
ISO 10993 Part 10-2021	Skin Sensitization Testing	Under the conditions of the study, the device is not a sensitizer	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
ISO 10993 Part 23-2021	Skin irritation Testing	Under the conditions of the study, the device is not an irritant	The test article met the requirements of the test since the difference

			between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the SC and SO test article extracts, respectively
ISO 10993-5:2009	Cytotoxicity testing	No Cytotoxicity reactivity	The test article extract showed evidence of causing severe cell lysis or toxicity. Toxicity concerns was addressed by Acute Systemic Toxicity testing.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.

- ASTM D6319-19 (2023), Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19 (2023), Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (2022), 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 (2023), 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 10: Tests For Skin Irritation.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

8. Summary of Clinical Testing

Clinical testing is not needed for this device.

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K240545.