August 19, 2021

Dezhou Purism Medical Technology Co., Ltd.
% Natalya Valerio
Consultant
mdi Consultants, Inc.
55 Northern Blvd., Suite 201
Great Neck, New York 11021

Re: K211319
Trade/Device Name: Purism Non-Sterile Powder Free Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 14, 2021
Received: July 16, 2021

Dear Natalya Valerio:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K211319

Device Name
Purism Non-sterile Powder Free Nitrile Examination Gloves

Indications for Use *(Describe)*
The Purism Non-sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

The assigned 510(k) number is: K211319

Date Summary Prepared: August 3, 2021

1. Submitter's Identification:

Dezhou Purism Medical Technology Co., Ltd.
High-end Equipment Manufacturing Park, Minsheng North Road,
Economic Development Zone, Pingyuan County,
Dezhou City, Shandong Province, 253100 China
Tel: +86 15662735157
Contact Person: Mengqi Yang

2. Name of the Device:

Device Trade Name: Purism Non-sterile Powder Free Nitrile Examination Gloves

3. Regulatory Information:

Regulation Name:	Non-Powdered Patient Examination Glove
Regulatory Class:	Class I, reserved
Product Code:	LZA
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital

4. Predicate Device Information:

510(k) #:	K210057
Device:	Blue Nitrile Exam Glove, Powder Free
Manufacturer:	Real Star Medical Technology Co., Ltd.

5. Device Description:

The Purism Non-sterile Powder Free Nitrile Examination Gloves are a non-sterile, powder free, single use, disposable item. The gloves are made from nitrile compound and are blue in color. The gloves are ambidextrous and offered in Small, Medium, Large and X-Large sizes.

6. Indications for Use:

The Purism Non-sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

7. Technological Comparison to the 510(k) Cleared Predicate Device:

Table 1: Comparison to Predicate Device

COMPARISON CRITERIA	NEW DEVICE 510(K) # K211319	PREDICATE DEVICE 510(K) # K210057	COMPARISON RESULT
Device Name	Purism Non-sterile Powder Free Nitrile Examination Gloves	Blue Nitrile Exam Glove, Powder Free	N/A
Manufacturer	Dezhou Purism Medical Technology Co., Ltd.	Real Star Medical Technology Co., Ltd.	N/A
Product Code	LZA	LZA	Same
Classification	Class 1	Class 1	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for Use	The Purism Non-sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The Blue Nitrile Exam Glove, Powder Free is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	Same
Sterile or Non-Sterile	Non-Sterile	Non-Sterile	Same
Reusable or Disposable (Single Use)	Disposable (Singe Use)	Disposable (Single Use)	Same
Design	Ambidextrous	Ambidextrous	Same
Material of Construction	Nitrile compound	Nitrile compound	Same
Size	S, M, L, XL	S, M, L, XL	Same
Color	Blue	Blue	Same

<table>
<tr><td>Powdered or Powder Free</td><td colspan="3">Powder Free</td><td colspan="3">Powder Free</td><td>Same</td></tr>
<tr><td rowspan="5">Glove Thickness</td><td>Size</td><td>Finger (mm)</td><td>Palm (mm)</td><td>Size</td><td>Finger (mm)</td><td>Palm (mm)</td><td rowspan="5">Similar
Both devices are within ASTM D6319-19 specifications</td></tr>
<tr><td>S</td><td>0.10±0.02</td><td>0.06±0.02</td><td>S</td><td>0.08±0.03</td><td>0.08±0.03</td></tr>
<tr><td>M</td><td>0.10±0.02</td><td>0.06±0.02</td><td>M</td><td>0.08±0.03</td><td>0.08±0.03</td></tr>
<tr><td>L</td><td>0.10±0.02</td><td>0.06±0.02</td><td>L</td><td>0.08±0.03</td><td>0.08±0.03</td></tr>
<tr><td>XL</td><td>0.10±0.02</td><td>0.06±0.02</td><td>XL</td><td>0.08±0.03</td><td>0.08±0.03</td></tr>
<tr><td rowspan="5">Glove Dimensions</td><td>Size</td><td>Min Length (mm)</td><td>Palm Width (mm)</td><td>Size</td><td>Min Length (mm)</td><td>Width (mm)</td><td rowspan="5">Similar
Both devices are within ASTM D6319-19 specifications</td></tr>
<tr><td>S</td><td>230</td><td>80±10</td><td>S</td><td>230</td><td>80±10</td></tr>
<tr><td>M</td><td>230</td><td>95±10</td><td>M</td><td>230</td><td>95±10</td></tr>
<tr><td>L</td><td>230</td><td>110±10</td><td>L</td><td>230</td><td>110±10</td></tr>
<tr><td>XL</td><td>230</td><td>≥110</td><td>XL</td><td>230</td><td>120±10</td></tr>
<tr><td colspan="7">Performance Testing</td><td></td></tr>
<tr><td>ASTM D6319-19
Physical Properties</td><td colspan="3"><u>Before Ageing</u>
Tensile Strength
min 14 MPa
Ultimate Elongation
min 500%

<u>After Ageing</u>
Tensile Strength
min 14 MPa
Ultimate Elongation
min 400%</td><td colspan="3"><u>Before Ageing</u>
Tensile Strength
min 14 MPa
Ultimate Elongation
min 500%

<u>After Ageing</u>
Tensile Strength
min 14 MPa
Ultimate Elongation
min 400%</td><td>Same</td></tr>
<tr><td>ASTM D5151-19
Freedom from Holes</td><td colspan="3">Passed at AQL 1.5</td><td colspan="3">Passed at AQL 2.5</td><td>Similar
Both devices are within ASTM D5151-19 requirements</td></tr>
</table>

ASTM D6124-06 Residual Powder	≤2 mg/glove		≤2 mg/glove	Same Both devices are within ASTM D6124- requirements
ISO 10993 Biocompatibility	Primary Skin Irritation ISO 10993-10:2010	Under the conditions of study not an Irritant	Under the conditions of study not an irritant	Same
	Dermal Sensitization ISO 10993-10:2010	Under the conditions of study not a Sensitizer	Under the conditions of study not a sensitizer	Same
	In vitro Cytotoxicity ISO 10993-5:2009	Under the conditions of Study Cytotoxic	Under the conditions of study non-cytotoxic	Different
	Acute Systemic Toxicity ISO 10993-11:2017	Under the conditions of study did not Show Systemic Toxicity	No data available	N/A

Both the Purism Non-sterile Powder Free Nitrile Examination Gloves and predicate Blue Nitrile Exam Glove, Powder Free are disposable, single use, non-sterile, powder free gloves intended for medical purposes to be worn on the examiner's hand to prevent contamination between patient and examiner.

Both gloves are similar in color, design and sizes. Both gloves are made of nitrile compound.

The only difference was in cytotoxicity test results where the Purism Non-sterile Powder Free Nitrile Examination Gloves showed cytotoxic properties under the conditions of the study. However, additional acute systemic toxicity testing performed under the ISO 10993-11:2017 supported the subject device was not systemically toxic. The results of primary skin irritation and dermal sensitization tests under the ISO 10993-10:2010 standard indicated the subject device was not an irritant or skin sensitizer.

8. Summary of Non-Clinical Tests Performed:

The non-clinical performance testing completed for the Purism Non-sterile Powder Free Nitrile Examination Gloves demonstrated that the subject device met the acceptance criteria or specification for the applicable test methodology or standard as shown below.

Table 2: Non-Clinical Tests

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine glove length	**Min Length (mm)**	**Avg Min Length (mm)**
		Size S: 230	Size S: 236 (Pass)
		Size M: 230	Size M: 239 (Pass)
		Size L: 230	Size L: 241 (Pass)
		Size XL: 230	Size XL: 238 (Pass)
	To determine glove palm width	**Palm Width (mm)**	**Avg Palm Width (mm)**
		Size S: 80±10	Size S: 84 (Pass)
		Size M: 95±10	Size M: 95 (Pass)
		Size L: 110±10	Size L: 103 (Pass)
		Size XL: ≥110	Size XL: 111 (Pass)
	To determine glove finger thickness	**Finger Thickness (mm)**	**Avg Finger Thickness (mm)**
		Size S: 0.100±0.02	Size S: 0.096 (Pass)
		Size M: 0.100±0.02	Size M: 0.111 (Pass)
		Size L: 0.100±0.02	Size L: 0.108 (Pass)
		Size XL: 0.100±0.02	Size XL: 0.111 (Pass)
	To determine glove palm thickness	**Palm Thickness (mm)**	**Avg Palm Thickness (mm)**
		Size S: 0.060±0.02	Size S: 0.058 (Pass)
		Size M: 0.060±0.02	Size M: 0.066 (Pass)
		Size L: 0.060±0.02	Size L: 0.074 (Pass)
		Size XL: 0.060±0.02	Size XL: 0.080 (Pass)
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine glove physical properties before and after ageing	**Before Ageing** Tensile Strength min 14 MPa Ultimate Elongation min 500%	**Before Ageing** Tensile Strength min 18.0 MPa (Pass) Ultimate Elongation min 694% (Pass)

		After Ageing Tensile Strength min 14 MPa Ultimate Elongation min 400%	**After Ageing** Tensile Strength min 18.2 MPa (Pass) Ultimate Elongation min 664% (Pass)
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To detect holes and check for water leaks	As per ISO 2859-1, GI Level II, Lot Size 3000, Sample Size 125, AQL 1.5, Ac=5, Re=6	Pass at AQL 1.5
ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves	To determine residual powder	≤2 mg/glove	0.06 mg/glove (Pass)

Table 3: Biocompatibility Tests

Test Method	Purpose	Acceptance Criteria	Results
Primary Skin Irritation ISO 10993-10:2010	To determine if device is a skin irritant	The device must be a non-irritant	Under the study conditions not an irritant
Dermal Sensitization ISO 10993-10:2010	To determine if device is a dermal sensitizer	The device must be a non-sensitizer	Under the study conditions not a sensitizer
In vitro Cytotoxicity ISO 10993-5:2009	To determine if device extract is cytotoxic	The device must be non-cytotoxic	Under the study conditions cytotoxic
Acute Systemic Toxicity ISO 10993-11:2017	To determine if device induces systemic toxicity	The device must not induce systemic toxicity	Under the study conditions did not induce systemic toxicity

9. Discussion of Clinical Tests Performed:

Clinical data are not required for marketing clearance of patient examination gloves.

10. Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K211319, Purism Non-sterile Powder Free Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K210057.