May 18, 2022

Hebei kangxida Medical Technology Development Co., Ltd.
℅ Bryan Wong
Associate
PureVision Ai Inc.
111 Town Square Place, Suite 1203
Jersey, New Jersey 07310

Re: K220211
Trade/Device Name: Nitrile Powder Free Examination Gloves (YK0001)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 29, 2022
Received: April 5, 2022

Dear Bryan Wong:

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,

Bifeng Qian, M.D., Ph.D.
Acting 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)*
K220211

Device Name
Nitrile Powder Free Examination Gloves (YK0001)

Indications for Use *(Describe)*
Nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger 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.

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

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510(k) Summary K220211

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor

- Company Name: Hebei Kangxida Medical Technology Development Co., Ltd.
- Address: No. 5, Chuangye Avenue, Weixian Economic Development Zone, Handan City, Hebei Province, China
- Phone: +86-15033056781
- Email: handanyingke@163.com
- Contact Person (including title): Liu Xiaomin (General Manager)
- Date of Preparation: Jan. 24, 2022

Application Correspondent:

- PureFDA
- Address: 111 Town Square Place, Suite 1203 Jersey City, NJ 07310-2784
- Contact Person: Bryan Wong
- Title: Associate
- Tel: +1 888 768 1688
- Email: bryan@purefda.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Patient Examination gloves
- Classification Name: Non-powdered Patient examination glove
- Trade Name: Nitrile Powder Free Examination Gloves
- Model: YK0001
- Review Panel: General Hospital
- Product Code: LZA
- Regulation Number: 21 CFR 880.6250
- Regulation Class: I

3. Predicate Device Information

- 510(k) number: K120970
- Sponsor: Tangshan Zhonghong Pulin Plastic Co., Ltd.

- Common Name: Patient Examination gloves
- Classification Name: Patient examination glove
- Trade Name: Powder Free Nitrile Patient Examination Gloves, Blue Color
- Review Panel: General Hospital
- Product Code: LZA
- Regulation Number: 21 CFR 880.6250
- Regulation Class: I

4. Device Description

Nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This glove is in blue color, non-sterile and can be available in four specifications: Small, Medium, Large, X large. It meets all of the requirements of ASTM standard D 6139-19.

5. Intended Use / Indications for Use

Nitrile powder free examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. Comparison to predicate device

Table 1-General Comparison

Device	Proposed Device	Predicate Device	Comparison
510(K)	K220211	K120970	--
Manufacturer	Hebei Kangxida Medical Technology Development Co., Ltd.	Tangshan Zhonghong Pulin Plastic Co., Ltd.	--
Product Name	Nitrile Examination Gloves	Powder Free Nitrile Patient Examination Gloves, Blue Color	--
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Product Code	LZA	LZA	Same
Color	Blue	Blue	Same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	Same
Design Feature	ambidextrous	ambidextrous	Same
Surface Feature	Smooth	Smooth	Same
Intended Use/	Nitrile powder free examination glove	Powder Free Nitrile Patient	Same

Indications for Use	is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.			Examination Glove, Blue Color 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.			
Device Description and Specifications	Meets ASTM D6319- 19			Meets ASTM D6319- 10			Same
Dimensions– Length ILS-2 AQL4.0 (ASTM D6319)	⩾230mm min for Small sizes ⩾240mm min for Medium / Large / X large sizes			Meets ASTM D6319-10 ⩾230mm min			Similar Note 1
Dimensions– Width IL S-2 AQL4.0 (ASTM D6319)	Small	85mm±10mm		Small	70-90 mm		
	Medium	95mm±10mm		Medium	85-105mm		
	Large	105mm±10mm		Large	100-120mm		
	X large	115mm±10mm		X large	110-130 mm		
Dimensions— Thickness IL S-2 AQL4.0 (ASTM D6319)	Finger	Thickness (mm) min. Finger 0.05		Finger	0.05mm min		
	Palm	Thickness (mm) min. Palm 0.05		Palm	0.05mm min.		
Physical Properties IL S-2 AQL4.0 (ASTM D6319)	Before Aging	Tensile Strength	⩾14MPa	Before Aging	Tensile Strength	⩾14MPa	Similar Note2
		Ultimate Elongation	⩾500%		Ultimate Elongation	⩾500%	
	After Aging	Tensile Strength	⩾14MPa	After Aging	Tensile Strength	⩾14MPa	
		Ultimate Elongation	⩾400%		Ultimate Elongation	⩾400%	
Freedom from Pinholes Inspection Level I AQL2.5 (ASTM D5151-06)	Meets • 21 CFR 800.20 • ASTM D6319-19			Meets • 21 CFR 800.20 • ASTM D6319-10			Same
Residual Powder (ASTM D 6124-06)	Meets ASTM D 6124-06 (Reaffirmation 2011) below 2mg of residual powder			Meets ASTM D 6124-06 (Reaffirmation 2011) below 2mg of residual powder			
Biocompatibility	Under the conditions of this study, the test article was a non irritant , non sensitizer and non Systemic Toxicity			Under the conditions of this study, the test article was a nonirritant or nonsensitizer			Similar Note 3

Comparison in Detail(s):

Note 1:

The difference in the dimensions does not raise additional questions for safety and effectiveness. All proposed devices are conducted the test according to ASTM D6319, the test results shown that the dimension of proposed device meet the requirements of standard.

Note 2:

The difference in the physical properties does not raise additional questions for safety and effectiveness. Proposed devices are conducted the test according to ASTM D6319, the test results shown that the physical properties of proposed device meet the requirements of standard.

Note 3:

Performance testing including biocompatibility evaluation has been performed on the proposed device. The test results shown that the performance of proposed device meet the requirements of standard and no potential biocompatibility issues.

7. **Summary for non-clinical testing**

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-1 Fifth edition 2018-08: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

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 D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

Table 2 Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Length(mm) Small: ≥230mm Medium: ≥230mm Large: ≥230mm X large: ≥230mm Width(mm) Small: 85±10mm Medium: 95±10mm Large: 110±10mm X large: 115±10mm			Length(mm) Small: 231-238/Pass Medium: 244-248/Pass Large: 245-249/Pass X large: 240-244/Pass Width(mm) Small: 85-86/Pass Medium: 96-97/Pass Large: 106-108/Pass X large: 113-114/Pass
		Thickness (mm) Finger Small: ≥0.05mm Medium: ≥0.05mm Large: ≥0.05mm X large: ≥0.05mm Palm Small: ≥0.05mm Medium: ≥0.05mm Large: ≥0.05mm X large: ≥0.05mm			Thickness (mm) Finger Small: 0.097-0.111/Pass Medium: 0.110-0.131/Pass Large: 0.110-0.129/Pass X large: 0.116-0.128/Pass Palm Small: 0.064-0.068/Pass Medium: 0.065-0.069/Pass Large: 0.060-0.065/Pass X large: 0.059-0.066/Pass
ASTM D5151	Watertightness Test for Detection of Holes	No water leakage			0/125/Pass
ASTM D6124	Powder Content	< 2mg			0.3-0.4mg/Pass
ASTM D6319 **ASTM D412**	Physical properties	Before Aging	Tensile Strength	≥14MPa	Meet the requirements of ASTM D6319 AQL 4.0
			Ultimate Elongation	≥500%	Meet the requirements of ASTM D6319 AQL 4.0
		After Aging	Tensile Strength	≥14MPa	Meet the requirements of ASTM D6319 AQL 4.0
			Ultimate Elongation	≥400%	Meet the requirements of ASTM D6319 AQL 4.0

ISO 10993-5	Cytotoxicity	Non- cytotoxicity	Under conditions of the study, device extract is cytotoxic.
ISO 10993-11	Acute systemic toxicity	Non-acute systemic toxicity	Under conditions of` the study, did not show acute systemic toxicity in vivo / Pass
ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, not an irritant/ Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer./ Pass

8. Summary for clinical test

Clinical performance is not deemed necessary.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Nitrile Powder Free Examination Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device K120970.