August 8, 2023

Raxwell Industrial LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

August 8, 2023
Re: K232008
Trade/Device Name: Disposable Medical Examination Nitrile Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 3, 2023
Received: July 6, 2023

Dear Dave Yungvirt:

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 -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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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)*

K232008

Device Name
Disposable Medical Examination Nitrile Gloves

Indications for Use *(Describe)*
The Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands 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: K232008
Date Prepared: August 01, 2023

1 Correspondent Contact Information

Bruce Cai (Contact Person)
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2 Submitter (Applicant)

Company name: Raxwell Industries LLC.
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* This is our first 510(k) submission for the below product, and there were no prior submissions for the subject device.

3 Manufacturer information

Company name: Longgang City Ailiya Arts Crafts Co., Ltd.
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4 DEVICE

Name of Device	Disposable Medical Examination Nitrile Gloves
Common Name	Medical examination gloves
Classification Name	Non-powdered Patient Examination Glove
Classification	Class I
Regulation Number	21 CFR 880.6250
Regulation Number	LZA
Review Panel:	General Hospital

5 PREDICATE DEVICE

Predicate Device 510k number: K213121
Predicate Device Manufacturer: Jiangsu Cureguard Glove Co., Ltd.

6 Device Description

6.1 Indications for use of the device:

The Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

6.2 Device Description:

Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This glove is in black color, non-sterile and can be available in six specifications: XS, S, M, L, XL, XXL. It meets all of the requirements of ASTM standard D6319-19.

7 Predicate Comparison

Table 7.1 Disposable Medical Examination Nitrile Gloves Predicate Comparison

Item	**Subject Device**	**Predicated Device (K213121)**	**Remark**
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Intended Use	The Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Disposable Nitrile Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Material	Nitrile	Nitrile	Same
Powder or powder free	Powder free	Powder free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Colorant	Black	Black/ Lavender/ Navy Blue/Burgundy	Different Analysis 1
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile.	Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile.	Same

Dimensions (mm)		Length (mm): XS/S: ≥220; M/L/XL/XXL: ≥230; Width(mm): XS: 70±10mm; S: 80±10mm; M: 95±10mm; L: 110±10 mm; XL: 120±10 mm; XXL: 130±10 mm		Length: XS/S: ≥220; M/L/XL: ≥230; Width: XS: 70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10.		Different Analysis 2
Thickness (mm)		Finger: ≥0.05; Palm: ≥0.05		Finger: ≥0.05; Palm: ≥0.05		Same
Physical Properties	Before Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	500% min	Ultimate Elongation	500% min	Same
	After Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	400%min	Ultimate Elongation	400%min	Same
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Same
Powder Content		Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124		Same
Biocompatibility		ISO 10993-5, under conditions of the study, device extract is cytotoxic		ISO 10993-5, under conditions of the study, device extract is cytotoxic		Same
		ISO 10993-10, under the conditions of the study, not an irritant or a sensitizer		ISO 10993-10, under the conditions of the study, not an irritant or a sensitizer		Same
		ISO 10993-11, under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.		ISO 10993-11, under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.		Same

Difference Analysis 1: The subject device (black) is a different color than the predicate devices (Black/ Lavender/ Navy Blue).

Difference Analysis 2: The physical dimensions are different as compared to the predicate device. The subject device (black) has an additional XXL size which was not presented in the predicate device. All proposed device sizes meet the requirements of ASTM D6319-19.

8 Summary of 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 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization.

ISO 10993-11:2017, 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.

ASTM D412-16e1, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension

ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems ANSI ASQ Z1.4-2003 (R2018), Sampling Procedures and Tables for Inspection by Attributes

Table 8.1 Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-19	Physical Dimensions Test	Length (mm): XS/S: ≥220; M/L/XL/XXL: ≥230; Width (mm): XS: 70±10 mm; S: 80±10 mm; M: 95±10 mm; L: 110±10 mm; XL: 120±10 mm; XXL: 130±10 mm	Length(mm): Pass XS/S: ≥220; Pass M/L/XL: ≥230; Width(mm): Pass XS: 74-77mm; S: 83-87 mm; M: 96-98 mm; L: 103-107 mm; XL: 112-115 mm; XXL: 120-123 mm;
		Thickness (mm): Finger: >0.05 Palm: >0.05	Thickness (mm): Finger: 0.123-0.182/Pass Palm: 0.112-0.140/Pass

ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151, AQL2.5			0/125/Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0 mg/glove			≤0.23mg/Pass;
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	19.4-55.9 MPa /Pass;
			Ultimate Elongation	≥500%	502.367-682.033% /Pass;
		After Aging	Tensile Strength	≥14MPa	22.4-58.6MPa /Pass;
			Ultimate Elongation	≥400%	504.365-663.243% /Pass;
ISO 10993-5	Cytotoxicity	Non cytotoxic			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
ISO 10993-10	Irritation	Non-irritating			Under the conditions of the study, not an irritant
ISO 10993-10	Sensitization	Non-sensitizing			Under conditions of the study, not a sensitizer.

9 Summary of Clinical Testing

Clinical testing is not needed for this device.

10 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Disposable Medical Examination Nitrile Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicated device in K213121.