April 9, 2022

Watchtower PPE Supplies Inc.
℅ Rafi Wong
Manager
Pacific Fortune Management Inc.
2350 Mission College Blvd, Ste 475
Santa Clara, California 95054

Re: K212929
Trade/Device Name: 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: March 15, 2022
Received: March 16, 2022

Dear Rafi 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

Appendix A: Indications for Use Statement

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)*

K212929

Device Name
Nitrile Examination Gloves

Indications for Use *(Describe)*

A powder free patient examination 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 device is for over-the-counter use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510K SUMMARY
K212929

Date of Summary Prepared: March 15, 2022

510K Number: K212929

1. Submitter Information

Submitter Contact:

Address:	WATCHTOWER PPE SUPPLIES, INC. 600 W John Street, Ste 140B, Hicksville, New York 11801, USA

Submitter Contact Person:

Name:	Riva Zheng
Phone Number:	(+1)646-717-6266
Email:	watchtowersupplies@gmail.com

Designated Submission Correspondent:

Name:	Rafi Wong
Phone Number:	+1 (408) 646-6537
Email:	rafi.wong@pfmfinance.com

2. Device Name: Nitrile Examination Gloves

3. Regulatory Information

Common Name:	Polymer Patient Examination Glove
Apparel Classification:	Class I
Product Code:	LZA
Regulation Number:	21 CFR 880.6250

4. **Predicate Device**

510K Number:	K192333
Company name:	JR Engineering & Medical Technologies (M) SDN.BHD.
Device Name:	Blue Nitrile Examination Gloves Powder Free
Cleared date:	January 24, 2020

5. **Intended Use/Indications for Use**

A powder free patient examination 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 device is for over-the-counter use.

6. **Device Description**

The proposed Nitrile Examination Gloves are ambidextrous, non-sterile, powder-free, Not made with natural rubber latex and is made of nitrile (Butyronitrile latex) . It has a finger textured surface and is colored blue. This is a single use, disposable device(s), provided non-sterile. The device is provided in 4 sizes, from small to extra-large.

7. **Summary of Comparison and Technological Characteristics**

Table I - General Comparison

Characteristics	**Acceptance Criteria**	**Proposed Device**	**Predicate Device**	**Comparison**
		Nitrile Examination Gloves	**Blue Nitrile Examination Gloves Powder Free**	
510K Number	/	K212929	K192333	-
Product Code	LZA	LZA	LZA	Same
Manufacturer	/	WATCHTOWER PPE SUPPLIES, INC.	JR Engineering & Medical Technologies (M) SDN.BHD.	Different
Classification	Class I (21 CFR 880.6250)	Class I (21 CFR 880.6250)	Class I (21 CFR 880.6250)	Same

Intended Use / Indications for Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. The device is for over- the-counter use.	A powder free patient examination 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 device is for over-the-counter use.	A powder free patient examination gloves 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.	Same
Material Use	Nitrile	Nitrile	Nitrile	Same
Color	Blue	Blue	Blue	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
<u>Dimensions (ASTM D6319- 19)</u>	Overall Length (mm) 220 mm = (sizes XS-S) 230 mm = (sizes M-XL)	Size: M Length Min: 230mm Palm Width Min: 95 +/-10mm Finger Thickness min: 0.05 mm Palm Thickness min: 0.05 mm	Size: M Length Min: 230mm Palm Width Min: 95+/-10mm Finger Thickness min: 0.05 mm Palm Thickness min: 0.05 mm	Same
	Width (±10 mm) Size S = 80 mm Size M = 95 mm Size L = 110 mm Size XL = 120 mm			
	Thickness at Finger (mm) All Sizes = 0.05mm			
	Thickness at Palm (mm)			

	All Sizes = 0.05mm			
Physical Properties	Before Aging ASTM D6319-19			
	Tensile Strength (MPa) = 14 min.	Tensile Strength (Mpa) ≥ 14 min.	Tensile Strength (Mpa) = 14 min.	Same
	Ultimate Elongation (%) = 500 min.	Ultimate Elongation (%) 500 min.	Ultimate Elongation (%) = 500 min.	Same
	After Aging ASTM D6319-19			
	Tensile Strength (Mpa) = 14 min.	Tensile Strength (Mpa) ≥ 14 min.	Tensile Strength (Mpa) ≥ 14 min.	Same
	Ultimate Elongation (%) = 400 min.	Ultimate Elongation (%) 400 min.	Ultimate Elongation (%) 400 min.	Same
Freedom from Holes (ASTM D5151)	AQL 2.5 Inspection Level G-1	Passes AQL-2.5	Passes AQL-2.5	**Same**
Residual Power (ASTM D6124)	≤ 2.0 mg/pc	≤ 2.0 mg/pc	≤ 2.0 mg/pc	**Same**

Biocompatibility	Primary Skin Irritation Test ISO 10993-10	Under the conditions of study, the test article showed no irritation on the skin.	Under the condition of study not an irritant.	Same
	Dermal Sensitization Assay ISO 10993-10	Under the conditions of study, there is no evidence that the test article extracts would cause sensitization on guinea pig.	Under the conditions of the study not a sensitizer.	Same
	In Vitro Cytotoxicity ISO 10993-5	Under the conditions of this study,the MEM test extracts would be considered cytotoxic potential.	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern.	Same
	Acute Systemic Cytotoxicity ISO 10993-11	Under the conditions of this study, there is no mortality or evidence of systemic toxicity from the extracts. The test met the test requirements.	Under the condition of the study the device extracts do not pose a systemic toxicity concern.	Same
	Material Mediated Pyrogenicity ISO 10993-11	Under the conditions of this study, the test article would be considered no febrile reaction. The test article meets the test requirements.	Not performed	N/A

8. Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Medical Glove Guidance Manual Document, issued on January 22, 2008

STANDARDS:

- ASTM D6319−19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151−19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124−06/(R)2017 Standard Test Method for Residual Powder on Medical Gloves
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993- 1: 2009/(R)2013 Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-2:2006/(R)2014 Biological Evaluation of medical devices - Part 2: Animal welfare requirements
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Table II. Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria			Results
ASTM D6319−19	Physical Dimensions Test	Length(mm): S:≥220; M/L/XL:≥230; Width(mm): S: 80±10; M: 95±10; L: 110±10; XL: 120±10			Length(mm): ＞240/Pass; Width(mm): S: 87-88 /Pass M: 96-97/ Pass L: 110/ Pass； XL:114-115/ Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Thickness (mm): S: Finger: 0.115-0.123/Pass Palm: 0.066-0.073/Pass M: Finger: 0.120-0.132/Pass Palm: 0.067-0.075/Pass L: Finger: 0.118-0.125/Pass Palm: 0.069-0.073/Pass XL: Finger: 0.113-0.120/Pass Palm: 0.068-0.072/Pass
	Physical properties	Before Aging	Tensile Strength	≥14MPa	30.7-38 MPa/Pass
			Ultimate Elongation	≥500%	500-525%/Pass
		After Aging	Tensile Strength	≥14MPa	22.4-41 MPa/Pass
			Ultimate Elongation	≥400%	457-516%/Pass

ASTM D5151−19	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5	0/200/Pass
ASTM D6124−06/(R)2017	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg	0.1mg/Pass;
ISO 10993-10: 2010	Irritation	Non-irritating	Under the conditions of the study, not anirritant/ Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer./ Pass
ISO 10993-11	To evaluate the potential for medical device materials to cause adverse systemic reactions	Non- systemic toxicity	Under conditions of the study, There was no evidence of systemic toxicity from the extract / Pass
ISO 10993-5	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	The viab.% of the 100% extract of the test article is the final result, and if viability is reduced to <70% of the blank, it has cytotoxic potential	Viab.% of 100% test article extract is 9.87% It means the proposed device have potential toxicity to L-929 in the MTT method/ Pass

9. Clinical Test

There is no clinical study included in this submission.

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device Nitrile Examination Gloves are as safe, as effective, and performs as well as or better than the predicate device, Blue Nitrile Examination Gloves Powder Free (K192333) manufactured by JR Engineering & Medical Technologies (M) SDN.BHD.