August 24, 2021

Shandong DS Safety Technology Co., Ltd.
℅ Rafi Wong
Manager
Pacific Fortune Management Inc.
2350 Mission College Blvd, Ste 475
Santa Clara, California 95054

Re: K210897
Trade/Device Name: Disposable 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 19, 2021
Received: July 26, 2021

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,

For Clarence W. Murray, III, Ph.D.
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)*

K210897

Device Name

Disposable 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.

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510K SUMMARY

Date of Summary Prepared: August 24,2021

510K Number: K210897

1. Submitter Information

Submitter Contact:

Address: SHANDONG DS SAFETY TECHNOLOGY CO.,LTD.
West of Yaoqian Road, Yaogezhuang Community,
Economic Development Zone, Gaomi City, Weifang City
Shandong 261502, China

Submitter Contact Person:

Name: Summer Feng

Phone Number: +86-0536-2586046

Email: summer@dsgloves.com

Designated Submission Correspondent:

Name: Rafi Wong

Phone Number: +1 (408) 646-6537

Email: rafi.wong@pfmfinance.com

2. Device Name: Disposable 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

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 Disposable Nitrile Examination Gloves are ambidextrous, non-sterile, powder-free, and is made of nitrile (Acrylonitrile-butadiene copolymer) and chemical additives. It has a finger textured surface and is colored blue. This is a single use, disposable device(s), provided non-sterile.

7. Summary of Comparison and Technological Characteristics

Table I - General Comparison

Characteristics	Acceptance Criteria	Proposed Device	Predicate Device	Comparison
		Disposable Nitrile Examination Gloves	Blue Nitrile Examination Gloves Powder Free	
510K Number	/	K210897	K192333	-
Product Code	LZA	LZA	LZA	Same
Manufacturer	/	SHANDONG DS SAFETY TECHNOLOGY CO.,LTD.	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	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

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
- AAMI / ANSI / ISO 10993-11: 2017 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- 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 - Performance Testing Comparison Table of proposed device K210897 and predicate device K192333

Characteristics	Acceptance Criteria	Proposed Device	Predicate Device	Comparison
		Disposable Nitrile Examination Gloves (K210897)	**Blue Nitrile Examination Gloves Powder Free (K192333)**	
Dimensions (ASTM D6319-19)	Overall Length (mm) 220 mm = (sizes XS-S) 230 mm = (sizes M-XL)	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	Same
	Width (± 10 mm) Size S = 80 mm Size M = 95 mm Size L = 110 mm Size XL = 120 mm	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-Finger (mm) All Sizes≥0.05mm		
	Thickness at Palm (mm) All Sizes = 0.05mm	Thickness-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

Table III - Biocompatibility Testing Comparison Table

Characteristics	**Acceptance Criteria**	**Proposed Device**	**Predicate Device**	**Comparison**
		Disposable Nitrile Examination Gloves	**Blue Nitrile Examination Gloves Powder Free**	
Biocompatibility	Primary Skin Irritation Test ISO 10993-10	Under the conditions of the test, the test article would be considered a non-irritant.	Under the condition of study not an irritant.	Same
	Dermal Sensitization Assay ISO 10993-10	Under the conditions of this study, there is no evidence of skin sensitization in guinea pigs was found.	Under the conditions of the study not a sensitizer.	Same
	Acute Systemic Test ISO 10993-11	Under the conditions of this study, there is no mortality or evidence of systemic toxicity from the extracts.	Under the condition of study the device extracts do not pose a systemic toxicity concern.	Same

		The test met the test requirements.		
	Material Mediated Pyrogenicity ISO 10993-11/ USP 41<151>	Under the conditions of this study, the test article would be considered no febrile reaction. The test article meets the test requirements.	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	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
	Intracutaneous Reactivity Test ISO 10993-10	The test result showed that the polar and non-polar extract of the final test sample score is less 1.0, the requirements of the test are met.	Not available.	N/A

9. Clinical Test

There is no clinical study included in this submission.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K210897, the Disposable Nitrile Examination Gloves , is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K192333.