October 29, 2021

Srirungruang Global Co., LTD.
% Aristotle Nafpliotis
Regulatory Affairs Consultant/Engineer
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K212308
Trade/Device Name: SHARK GLOVES Blue Nitrile Examination Gloves Powder Free, INCONGLOVE Blue Nitrile Examination Gloves Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 27, 2021
Received: September 28, 2021

Dear Aristotle Nafpliotis:

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,

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)*

K212308

Device Name
SHARK GLOVES Blue Nitrile Examination Gloves Powder Free
INCONGLOVE Blue Nitrile Examination Gloves Powder Free

Indications for Use *(Describe)*

SHARK GLOVES and INCONGLOVE Blue Nitrile Examination Gloves Powder Free are disposable devices intended for medical purpose that are 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: K212308.

1. Submitter's Identification:

Name: **SRIRUNGRUANG GLOBAL CO., LTD**
Address: 51/7 MOO 1, MABPHAI, BANBUNG, CHONBURI 20170 THAILAND
Phone no.: +66(0)38 151671
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Contact person: Mr.Suttichai Sripradub
Designation: Managing Director

Manufacturer:

Name: **SRIRUNGRUANG GLOBAL CO., LTD**
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Exporter: SRIRUNGRUANG GLOBAL CO., LTD.

Date Summary Prepared: May 31, 2021

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2. Device Identification

Name of the Device:	SHARK GLOVES Blue Nitrile Examination Gloves Powder Free INCONGLOVE Blue Nitrile Examination Gloves Powder free
Trade Name (s):	SHARK GLOVES, INCONGLOVE
Common or usual name:	Exam Gloves
Regulation Number:	21 CFR 880.6250
Regulation Name:	Non-powdered patient examination gloves.
Regulatory Class:	I
Product Code:	LZA
Review Panel:	General Hospital

3. Information for the 510(k) Cleared Device (Predicate Device):

Predicate Device:	JR MEDIC Blue Nitrile Examination Gloves Powder Free
Owner:	JR Engineering & Medical Technologies (M) SDN.BHD.
510(k) Number:	K192333
Regulatory Class:	I
Product Code:	LZA

4. Device Description:

SHARK GLOVES and INCONGLOVE Blue Nitrile Examination Gloves Powder Free are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250).

The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are blue in color and are powder free

5. Indications for Use:

SHARK GLOVES and INCONGLOVE Blue Nitrile Examination Gloves Powder Free are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner

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6. Technological Characteristic Comparison of Proposed and Predicate Devices:

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		PREDICATE	SUBJECT	
510(k) Number		K192333	K212308	-------
Name of device		Blue Nitrile Examination Gloves Powder Free	SHARK GLOVES and INCONGLOVE	-------
Dimensions	ASTMD6319-10 (Reapproved 2015) ASTMD6319-19	Length Min 230 mm Width Min 95+/-10 mm(for medium size)	Length Min 230 mm Width Min 95+/-10 mm(for medium size)	Same
Physical Properties	ASTMD6319-10 (Reapproved 2015) ASTMD6319-19	Before Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 500% After Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Before Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 500% After Aging Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Similar
Thickness	ASTMD6319-10 (Reapproved 2015) ASTMD6319-19	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Free, Powder residue	ASTMD6319-10 ASTMD6319-19	≤2 mg/glove	≤2 mg/glove	Similar

Biocompatibility	Primary Skin Irritation-ISO 1993-10:2010(E)	Under the condition of study not an irritant	Under the condition of study not an irritant	Same
	Dermal Sensitization-ISO 10993-10:2010(E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern	Similar
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the condition of study the device extracts do not pose a systemic toxicity concern	Under the condition of study the device extracts do not pose a systemic toxicity concern	Similar
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	Similar

Water Tight (1000 ml), Freedom from holes	ASTM D5151-06 ASTM D5151-19	Passes AQL-2.5	Passes	Similar
Indications for Use		JR MEDIC Blue Nitrile Examination Gloves Powder Free is disposable device intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	SHARK GLOVES and INCONGLOVE Blue Nitrile Examination Gloves Powder Free are disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Similar
Material	ASTMD6319-10(Reapproved ASTMD6319-19	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger texture	Same
Size	ASTMD6319-10 (Reapproved 2015) ASTMD6319-19	Extra Small, Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	SRIRUNGRUANG GLOBAL CO., LTD. 51/7 MOO 1, MABPHAI, BANBUNG ,CHONBURI 20170 THAILAND	------

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standards.

7. Summary of Non-Clinical Testing:

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Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes	Small: Pass Medium: Pass Large: Pass X-Large: Pass
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Small: -80+/-10 mm Medium: -95+/-10mm Large: -110+/-10 mm X-Large: -120+/-10 mm	Small: Pass Medium: Pass Large: Pass X-Large: Pass

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Size Small Medium Large X-large	Palm Pass	Finger Pass
ASTM D6319-19 Standard Specification physical properties- for Nitrile Examination Gloves Ultimate Elongation for Medical Application	To Determine the physical properties Tensile strength	**Before Ageing** Tensile Strength 14Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all size	Size Small Medium Large X-large	 Pass	 Pass
	To Determine the physical properties Ultimate Elongation	Before Ageing Ultimate Elongation 500% Min for all Size After Ageing	Size Small Medium	Before ageing Pass	After ageing Pass

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		Ultimate Elongation 400% Min for all sizes	Large X-large		

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-19 Standard Test Method for detection of holes in medical gloves	To determine the holes in the gloves	AQL 2.5	Pass	
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	Size Small Medium Large X-Large	Residual Powder Content Pass

The indications for use, materials, size and models are all similar. Both the subject and predicate devices are shown to be biocompatible and meet the specifications of the ASTM standard D6319-10.

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result

ISO 10993-10:2010 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation.	To determine the potential of the material under test to produce dermal irritation in Rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO10993-10:2010 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done Skin sensitization.	To determine the skin sensitization potential of the material both in terms of induction and elicitation in Guinea Pig.	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer
ISO 10993-5:2009 biological evaluation of medical devices - part 5, tests for in vitro cytotoxicity.	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method.	Under the conditions of study non cytotoxic	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern.
ISO 10993-11:2017 biological evaluation of medical devices - part 11, tests for systemic toxicity.	To determine the acute systemic toxicity potential of the test item extracts (both inside and outer surfaces) in swiss Albino mice.	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Under the conditions of study the device extracts do not pose a systemic toxicity concern

8. Discussion of Clinical Tests Performed:

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9. Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.