September 15, 2022

Lalan Rubbers (Pvt) Ltd
Renuka Priyangi
Manager - Quality Assurance
No.95/B, Zone A, Export Processing Zone, Biyagama
Malwana, Western EPZ 11672
Sri Lanka

Re: K220697
Trade/Device Name: Nitrile Patient 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: June 29, 2022
Received: August 26, 2022

Dear Renuka Priyangi:

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.
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)*
K220697

Device Name
Nitrile Patient Examination Gloves, Powder Free

Indications for Use *(Describe)*
Nitrile Patient Examination Gloves, Powder Free, are intended for medical purposes that are worn on the examiners' 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
K220697

APPLICANT

Company Name	Lalan Rubbers (Pvt) Ltd
Address	No.95/B, Zone A, Export Processing Zone, Biyagama, Malwana, Sri Lanka, EPZ 11672

CONTACT PERSON

Name	Renuka Priyangi
Designation	Manager - QA
Telephone	0094716852746
Fax	0094114311222
Email	qa@lalangroup.com

DATE PREPARED September 15, 2022

DEVICE

Trade Name	Nitrile Patient Examination Gloves, Powder Free
Common Name	Nitrile Patient Examination Gloves
Classification	Nitrile Patient Examination Gloves
Product Code	LZA
Device Class	Class I
C.F.R. Section	21 CFR 880.6250
Classification Panel	General Hospital

LEGALLY MARKETED PREDICATE DEVICE

Product Owner	Primus Gloves Private Limited
Trade name	Primus Nitrile Examination Gloves
510(k) Number	K143477
Device Class	Class I
Product code	LZA

DEVICE DESCRIPTION

The Nitrile Patient Examination Gloves, Powder Free are non-sterile, single use only, disposable, and powder free examination gloves. The glove is made of synthetic nitrile latex compound. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM D 6319 - Standard specification for Nitrile Examination Gloves for Medical Application.

Characteristic

Sterility	Non Sterile
Material	Nitrile
Surface treatment	Inner chlorinated outer polymer coated

Color	Blue
Geometry	Ambidextrous
Texture	Full textured
Cuff end finishing	Beaded
Usage	Single use & Over-the counter
Target Population	Adults
Available sizes	Ex Small, Small , Medium , Large, Ex Large
Shelf life	3 Years

INDICATIONS FOR USE STATEMENT

Nitrile Patient Examination Gloves, Powder Free, are intended for medical purposes that are worn on the examiners' hands to prevent contamination between patient and examiner.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Predicate Device	**Proposed Subject Device**	**Comparison Result**
Trade name	Primus Nitrile Examination Gloves	Nitrile Patient Examination Gloves, Powder Free	Not applicable
510k Number	K143477	K220697	Not Applicable
Product Owner	Primus Gloves Private Limited	Lalan Rubbers (Pvt) Ltd	Not Applicable
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Regulatory Class	1	1	Same
Regulation Name	Patient Examination Glove	Patient Examination Glove	Same
Classification Panel	General Hospital	General Hospital	Same
Target Population	Adults	Adults	Same
Intended Use/ Indications for Use	The Nitrile Patient Examination gloves, Powder free, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.	Nitrile Patient Examination Gloves, Powder Free, are intended for medical purposes that are worn on the examiners' hands to prevent contamination between patient and examiner.	Same
Material Composition	Synthetic nitrile rubber	Synthetic nitrile rubber	Same
Design	Non-sterile	Non-sterile	Same
	Single use	Single use	Same
	Powder-free	Powder-free	Same

		Ambidextrous	Ambidextrous	Same
		Beaded cuff	Beaded cuff	Same
Sterility		Non-sterile	Non-sterile	Same
Shelf Life		3 years	3 years	Same
Performance a. Dimensions		Meets ASTM D6319 requirements	Meets ASTM D6319 requirements	Same
b. Physical Properties		Meets ASTM D6319 requirements	Meets ASTM D6319 requirements	Same
c. Freedom from holes		Meets ASTM D6319 requirements of GI, AQL 2.5	Meets ASTM D6319 requirements of GI, AQL 2.5	Same
d. Powder Residual		Meets ASTM D6319 requirements; Not more than 2.0mg/glove	Meets ASTM D6319 requirements; Not more than 2.0mg/glove	Same
e. Sterility		Non-sterile	Non-sterile	Same
Biocompatibility	Skin Irritation	Under the conditions of the study not an irritant	Under the conditions of the study not an irritant	Same
	Skin Sensitization	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	In Vitro Cytotoxicity	No data available	Under the conditions of the study for diluted concentrations 12.5% and 6.25% are not cytotoxic. Undiluted extract (100%) ,diluted concentrations 50% & 25% are cytotoxic.	Similar
	Acute Systemic Toxicity	No data available	Under the conditions of the study no evidence of systemic toxicity	Similar

DISCUSSION OF NON-CLINICAL TESTS PERFORMED

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

- ASTM, D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- 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
- ISO, 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO,10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO,10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- ISO,10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN, 455-4:2009, Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

Characteristics	Standard/Specification	Result Summary
1. Physical Characteristics:		
1.1 Dimensions	*ASTM D6319*	*Meets ASTM D6319 requirements for length, palm width and thickness*
Length	*Minimum 230mm*	*Minimum 240mm*
Palm width (mm)		
Size – XS	*70 ± 10*	*≤ 80*
Size – S	*80 ± 10*	*85±5*
Size – M	*95 ± 10*	*95±5*
Size – L	*110± 10*	*105±5*
Size - XL	*120 ± 10*	*≥ 110*
Thickness (mm) - single-wall		
Finger	*minimum 0.05*	*Finger – 0.09 ± 0.01*
Palm	*minimum 0.05*	*Palm – 0.07 ± 0.01*
Cuff	*-*	*Cuff – 0.05 ± 0.01*

1.2 Physical Properties	*ASTM D6319*	*Meets ASTM D6319 requirements for tensile strength and ultimate elongation before and after accelerated aging*
Tensile Strength		
Before Aging	*minimum 14 MPa*	*minimum 14 MPa*
After Aging	*minimum 14 MPa*	*minimum 14 MPa*
Ultimate Elongation		
Before Aging	*minimum 500%*	*minimum 500%*
After Aging	*minimum 400%*	*minimum 400%*
2. Freedom from holes	*ASTM D6319* *ASTM D5151*	*Meets ASTM D6319 and ASTM D5151 requirements of AQL 2.5*
3. Powder Residual	*ASTM D6319* *ASTM D6124*	*Meets applicable requirement for powder free; ≤ 2 mg per glove*
4. Biocompatibility		
Skin Irritation Test	*ISO10993-23:2021*	Under the conditions of the study, not an irritant
Skin Sensitization Test (GPMT)	*ISO 10993-10:2010*	Under the conditions of the study, not a sensitizer
In Vitro Cytotoxicity	*ISO 10993-5:2009*	Under the conditions of the study, diluted concentrations 12.5% and 6.25% are not cytotoxic. Undiluted extract (100%) ,diluted concentrations 50% & 25% are cytotoxic.
Acute Systemic Toxicity	*ISO 10993-11: 2017*	Under the conditions of the study, no evidence of systemic toxicity

DISCUSSION OF CLINICAL TESTS PERFORMED

Clinical testing is not needed for this device.

CONCLUSION

The conclusions drawn from the non-clinical tests demonstrate that Nitrile Patient Examination Gloves, Powder Free is as safe as effective, and performs as well as or better than the legally marketed predicate device previously cleared under K143477.