



February 17, 2022

Amazing Rubber Products Pvt Ltd  
% Manoj Zacharias  
Consultant  
Liberty Management Group Ltd  
75 Executive Dr, STE 114  
Aurora, Illinois 60504, USA

Re: K212586

Trade/Device Name: Sterile Nitrile Patient Examination Gloves Powder Free Blue Color  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Non-Powdered Patient Examination Glove  
Regulatory Class: Class I, reserved  
Product Code: LZA  
Dated: January 19, 2022  
Received: January 19, 2022

Dear Manoj Zacharias:

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K212586

Device Name

Sterile Nitrile Patient Examination Gloves Powder Free Blue Color

Indications for Use (Describe)

Sterile Nitrile Patient Examination Gloves Powder Free Blue Color is a disposable device intended for medical purpose that is 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**  
**K212586**  
**As required by: 21CFR§807.92(c)**

**A. APPLICANT INFORMATION**

510(K) Owner's Name	Amazing Rubber Products Pvt. Ltd.
Address	Plot No 14c, Cochin Special Economic Zone , Kakkanad, Cochin-682 037, Kerala- India
Phone	9447053062
Fax	-----
E-mail	info@amazingglove.com
Contact Person	Mr. Jayasankar. S
Designation	Executive Director
Contact Number	9447053062
Contact Email	info@amazingglove.com
Date Submitted	14 January 2022

**B. DEVICE IDENTIFICATION**

Name of the device	Sterile Nitrile Patient Examination Gloves Powder Free Blue Color
Product proprietary or trade name	<b>Amazing<sup>+</sup></b>
Common or usual name	Exam Gloves
Classification name	Patient Examination Gloves
Device Classification	Class-1
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

**C. PREDICATE DEVICE**

Predicate Device	Sancare Sterile Nitrile Patient Examination Gloves, Powder free Blue Colour
510( K) Number	K171093
510 (K) Owner	Sanrea Healthcare Products Pvt. Ltd.
Regulatory Class	1
Product code	LZA

**D. DESCRIPTION OF THE DEVICE:**

Sterile Nitrile Patient Examination Gloves Powder Free Blue Color 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. Both Gamma & ETO sterilized gloves are available in X-Small, Small, Medium, Large & X-Large sizes.

**E. INTENDED USE OF THE DEVICE:**

Sterile Nitrile Patient Examination Gloves Powder Free Blue Color is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

**F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATEDEVICE**

Characteristics	Standards	Device Performance		Remarks
		Predicate	Subject	
510(K) Number		<b>K171093</b>	<b>K212586</b>	----
Name of device		Sancare Sterile Nitrile Patient Examination Gloves, Powder free Blue Colour	Sterile Nitrile Patient Examination Gloves Powder free Blue Color	Similar
Dimensions	ASTM D6319- 2019	Length Min 230 m Width Min 95+/-10 mm(for medium size)	Length Min 230 mm Width Min 95+/-10 mm(for medium size)	Same
Physical Properties	ASTM D6319- 2019	<b><u>Before Aging</u></b> Tensile Strength min 14 Mpa Ultimate Elongation Min 500% <b><u>After Aging</u></b> Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	<b><u>Before Aging</u></b> Tensile Strength min 14 Mpa Ultimate Elongation Min 500% <b><u>After Aging</u></b> Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Same
Thickness	ASTM D6319-2019	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Residue	ASTM D6214	≤2 mg/glove	≤2 mg/glove	Same
Biocompatibility	Primary Skin Irritation- ISO 10993-10:2010( 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)	No data available	Under the conditions of the study, cytotoxic	----
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	No data available	Under the condition of study do not pose a systemic toxicity concern	----
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	No data available	Under the conditions of the study non pyrogenic	----
	Bacterial Endotoxin test USP 42<85>	No data available	<20EU/pair of gloves	----

Characteristics	Standards	Device Performance		Remarks
		Predicate K171093	Current K212586	
Water Tight (1000 ml)	ASTM D5151-2019	Passes AQL-1.5	Passes AQL-1.5	Similar
Intended use		The Sterile 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.	The Sterile Nitrile Patient Examination gloves Powder free, Blue color, is a disposable device intended for medical purposes that is worn on the examiners' hand to prevent contamination between Patient and examiner.	Similar
Material	ASTM D6319-2019	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger texture	Same
Size	ASTM D6319-2019	Extra Small, Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Sterile- ETO/as well as Radiation, SAL- 10 <sup>-6</sup>	Sterile -ETO/as well as Radiation, SAL- 10 <sup>-6</sup>	Same
Manufacturer(s)	-	Sanrea Healthcare Products Pvt. Ltd.	Amazing Rubber Products Pvt. Ltd	-----

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 standard D6319.

### G. Non-Clinical Testing Summary

#### PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 220 mm for X-small and Small sizes Min 230 mm for other sizes	X-Small:- 303 mm Small:- 304 mm Medium:- 305mm Large:- 306mm X-Large:- 307mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	X-small:- 70+/-10 mm Small:- 80+/-10 mm Medium:- 95+/-10mm Large:- 110+/-10 mm X-Large:- 120+/-10 mm	X-small- 74 mm Small:- 84 mm Medium:- 94 mm Large:- 104 mm X-Large:- 115 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	<b>Size</b> X-Small Small Medium Large X-Large	<b>Palm</b> 0.10mm 0.10mm 0.10mm 0.10mm 0.10mm	<b>Finger</b> 0.12mm 0.12mm 0.12mm 0.12mm 0.12mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties- Tensile strength	<b>Before Ageing</b> Tensile Strength 14Mpa Min for all sizes <b>After Ageing</b> Tensile Strength 14Mpa Min for all sizes	<b>Size</b> X-Small Small Medium Large X-Large	<b>Before ageing</b> 18.44Mpa 18.49Mpa 18.56Mpa 18.62Mpa 18.64Mpa	<b>After ageing</b> 17.49Mpa 17.53Mpa 17.65Mpa 17.71Mpa 17.76Mpa
	To Determine the physical properties- Ultimate Elongation	<b>Before Ageing</b> Ultimate Elongation 500% Min for all sizes <b>After Ageing</b> Ultimate Elongation 400% Min for all sizes	<b>Size</b> X-Small Small Medium Large X-Large	<b>Before ageing</b> 683% 687% 692% 695% 698%	<b>After ageing</b> 656% 660% 663% 666% 669%

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-2019 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 1.5	
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	<b>Size</b> X-small Small Medium Large X-Large	<b>Residual Powder Content</b> 0.21mg/glove 0.21mg/glove 0.22 mg/glove 0.22 mg/glove 0.22 mg/glove

## BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological Evaluation of Medical Devices Test for Skin 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
ISO 10993-10 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.
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
Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	To determine the pyrogenic potential of the test item extract following intravenous injection in New Zealand white Rabbits.	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.
Bacterial Endotoxin test USP 42<85>	To determine the bacterial Endotoxin limit in the glove	NMT20 EU/pair of gloves	<20 EU/pair of gloves

## H. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(K) Process

## I. CONCLUSION

The conclusions drawn from the non clinical test demonstrate that the subject device in 510(K) submission, Sterile Nitrile Patient Examination Gloves Powder Free Blue Color is as safe, as effective, and performs as well as or better than the legally marketed predicate device K171093.