October 24, 2019

Lenora Glove PVT LTD.
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Drive
Ste 114
Aurora, Illinois 60504

Re: K190632
Trade/Device Name: Latex Surgeon's Gloves Powder Free with protein content labeling claim of 50µg/dm^2 or less per glove of extractable protein
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: September 18, 2019
Received: September 24, 2019

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190632

Device Name
Latex Surgeon's Gloves Powder Free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein

Indications for Use *(Describe)*

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination

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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LENORA GLOVE PVT.LTD.
SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR LATEX SURGEON'S GLOVE POWDER FREE

510K SUMMARY as required by: 21CFR § 807.92 K190632

A. APPLICANT INFORMATION

1.	Submitter Name	LENORA GLOVE PVT. LTD.
	Date Submitted	September 18, 2019
	Address	Plot No:15/104-1, Rottigoundanur, Thirumalayampalayam P.O., Coimbatore, Tamilnadu State, India-641 105
	Phone	+91 422 2656 443, 2656 941
	Fax	1 (815) 986-2632
	E-mail	qa@lenoraglove.com
	Contact Person	ANTONY KURIYAN
	Designation	Managing Director
	Contact Number	+91 974700797
	Contact Email	qa@lenoraglove.com

B. US AGENT & CONTACT PERSON INFORMATION

	US agent & contact person name	Manoj Zacharias
	Address	Liberty Management Group Ltd. 75 Executive Dr. STE 114, Aurora, IL-60504, USA.
	Phone	(630) 270-2921
	Fax	(815) 986-2632
	E-mail	manoj@libertymanagement.us

C. DEVICE IDENTIFICATION

	Common Name	Surgeon's Glove
	Device Name	Latex Surgeon's Glove powder free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein
	Product proprietary or trade name	Latex Surgeon's Glove powder free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein
	Classification name	Surgeon's Glove
	Device Classification	1
	Product Code	KGO
	Regulation Number	21 CFR 878.4460
	Review Panel	Gen & Plastic Surgery

D. PREDICATE DEVICE INFORMATION

	Name of devices	510k Number	510K Owner
Predicate device	"PRISTEEN" Latex Surgeon's Glove powder free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein	K172942	Beta Health Care products Pvt.Ltd,Plot No 21B, Cochin Special Economic Zone,Kakkanad, kerala, India-682037
Reference device	"Medismart+" Latex Surgeon's Glove powder free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein	K151114	St.Marys Rubbers Pvt.Ltd, Koovappally P.O, Kanjirappally, Kottayam District, Kerala State, India-686518

E. DESCRIPTION OF THE DEVICE

The proposed device, Latex Surgeon's Gloves Powder Free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein is a sterile and disposable medical glove intended to be worn by operating room personnel to protect a surgical wound from contamination.

The proposed device is made of' natural rubber latex, as per standard ASTM D35 77-09(2015).

The classification is: Type I - gloves compounded primarily from natural rubber latex".

The proposed device is Powder Free Latex Surgeon's Gloves, and variants of different sizes.

All variants share the same color, creamy, white.

The proposed device is sterilized either using Ethylene Oxide Sterilization or Gamma irradiation method to achieve the Sterility Assurance Level (SAL) of 10^{-6} and place in a sterility maintenance package to ensure a shelf life of 3 years.

F. INDICATION FOR USE

A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

G. TECHNOLOGICAL COMPARISON

a. General Characteristics Comparison

Characteristic	Subject device K190632	Predicate device K172942	Reference device K151114	Comparison
Product Code	KGO	KGO	KGO	Same
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	Same
Class	1	1	1	Same
Intended Use for Latex Surgeon's Gloves Powder Free, with protein content labeling claim of 50µg/dm² or less per glove of extractable protein.	A latex surgeon's glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. .	A latex surgeon Surgeons glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination	A latex surgeon Surgeons glove is a device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination	Similar
Powdered or Powder free	Powder free	Powder free	Powder free	Same
Method of powder free	Polymer coat	same	same	Same
Classification per ASTMD3577-99	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	Same
Sterilization	ETO/as well as Radiation, SAL- 10^{-6}	ETO/as well as Radiation, SAL- 10^{-6}	ETO/as well as Radiation, SAL- 10^{-6}	Same
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements	Same
Special label claim	Protein content labeling claim of 50 µg/dm² or less per glove of extractable protein for Latex Surgeon's Gloves Powder Free.	Same	same	Same
Type of use	Over the counter use	Over the counter use	Over the counter use	Same

b. Technological Characteristics Comparison

Characteristics	Acceptance criteria of the standard			Comparison
	Subject device K190632	Predicate device K172942	Reference device K151114	
Dimensions	ASTM D3577-09((Reapproved 2015))	ASTM D3577	ASTM D3577	Similar
Physical Properties	ASTM D3577-09 (Reapproved 2015)	ASTM D3577	ASTM D3577	Similar
Freedom from Holes	ASTM D3577 and AST MD5151-06, (Reapproved 2015)	ASTM D3577 and AST M D5151	ASTM D3577 and AST M D5151	Similar
Powder residue for powder free glove	ASTM D3577 and ASTM D6124-06, (Reapproved 2017) Powder content < 2 mg/Glove	ASTM D3577 and ASTM D6124, Powder content < 2 mg/Glove	ASTM D3577 and ASTM D6124, Powder content < 2 mg/Glove	Similar
Protein Content	ASTM D3577, ASTM D5712-15 and ASTM D6499-16	ASTM D3577, ASTM D5712 and ASTM D6499	ASTM D3577, ASTM D5712 and ASTM D6499	Similar
Biocompatibility (Irritation, Sensitization, Acute Systemic Toxicity)	ISO 10993-10 Non- irritant, Non-Sensitizer and Non-Toxic	ISO 10993-10	ISO 10993-10	Similar

H. Summary of Non-Clinical Testing

Bench tests were conducted to verify that the proposed device met all design specifications as the predicate devices. The standards used in this submission and the test results demonstrated that the proposed device complies with the following standards:

- ASTM D3577-09 (2015):- Standard Specification for Rubber Surgical Gloves.
- ASTM D 5151-06(2015):-Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06(2017):-Standard Test Method for Residual Powder on Medical Gloves.

- ASTM D5712-15:-Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method.

- ASTM D6499-18:-Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products.

- ASTM F 1929-2015:-Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

- ISO 11137-1-2006/ (R) 2010 validation of sterilization process.

- ISO 11137-2:2013, Sterilization of health care products - radiation - part 2: establishing the sterilization dose

- 1S01137-2:2013: Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.

- ISO 10993-7:2008:-Biological evaluation of medical devices —: Ethylene oxide sterilization residuals.

- ISO 11135-1:2014:-Sterilization of healthcare products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medicaldevices.

A summary of the non-clinical testing results for the subject device is provided below. The standards used in this submission and the test results demonstrate that the proposed device meets the acceptance criteria for the referenced standards.

SIZES AVAILABLE: - 5'/2, 6, 6'/2, 7, 7'/2, 8, 8'/2, 9

	CRITERIA	SPECIFICATION AS PER ASTMD3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTMD3577 - 09 STANDARD
1	Length ASTM D3577-09			
	Size 5'/2	Min 265mm	282 mm	Yes
	Size 6	Min 265mm	282mm	Yes
	Size 6'/2	Min 265mm	282mm	Yes
	Size 7	Min 265mm	282mm	Yes

	Size 7'/2	Min 265mm	282mm	Yes
	Size 8	Min 265mm	282mm	Yes
	Size 8'/2	Min 265mm	282mm	Yes
	Size 9	Min 265mm	282mm	Yes
2	Width ASTM D3577-09			
	Size 5'/2	70+/-6mm	71mm	Yes
	Size 6	76+/-6mm	78mm	Yes
	Size 6'/2	83+/-6mm	82mm	Yes
	Size 7	89+/-6mm	90mm	Yes
	Size 7'/2	95+/-6mm	95mm	Yes
	Size 8	102+/-6mm	100mm	Yes
	Size 8'/2	108+/-6mm	106mm	Yes
	Size 9	114+/-6mm	112mm	Yes
3	Finger Thickness (All sizes)	Min 0.10mm	0.20mm	Yes
4	Palm Thickness (All sizes)	Min 0.10mm	0.16mm	Yes
5	Cuff Thickness (All sizes)	Min 0.10mm	0.13mm	Yes

	CRITERIA	SPECIFICATION AS PER ASTMD3577-09 STANDARD	AVERAGE VALUE OF SUBJECT DEVICE	WHETHER SUBJECT DEVICE COMPLIED WITH THE ASTMD3577 -09 STANDARD
6	Tensile Strength ASTM D3577-09			
	Before aging (All sizes)	24Mpa minimum	26.5Mpa	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	18Mpa minimum	21.0Mpa	Yes
7	Ultimate Elongation ASTM D3577-09			
	Before aging (All sizes)	750% minimum	860%	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	560% minimum	725%	Yes
8	Stress at 500% before ageing (All sizes)	5.5 MPa Max	2.6 Mpa	Yes
9	Pinhole AQL ASTM D 5151-06(2015)			
	Before aging (All sizes)	Max 1.5	1.0	Yes
	After aging@ 70°C for 7 days (All sizes)	Max 1.5	1.0	Yes

I. Conclusion

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