March 10, 2020

JR Engineering & Medical Technologies (M) SDN.BHD.
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr, STE 114
Aurora, Illinois 60504

Re: K192328
Trade/Device Name: JR MEDIK Latex Surgeon's Gloves Sterile Powder Free
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: February 12, 2020
Received: February 14, 2020

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
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)*
K192328

Device Name
JR Medic Latex Surgeon's Gloves Sterile Powder Free

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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510K SUMMARY

K192328

as required by: 21 CFR § 807.92

A. APPLICANT INFORMATION

Submitter Name	JR Engineering & Medical Technologies (M) SDN.BHD.
Date Submitted	24th Nov 2019
Address	Lot 8 &10, Jalan Zurah 3 & Lot 1 & 3, Jalan Zurah 3A/1, Pusat Perindustrian 2, 44200 Rasa, Hulu Selangor, Selangor Darul Ehsan, Malaysia.
Phone	+603-60572081
Fax	+603-60572181
E-mail	ganeshjrmt@gmail.com
Contact Person	Mr. Ganesan Subramaniam
Designation	Managing Director
Contact Number	+6012 224 6677
Contact Email	ganeshjrmt@gmail.com

B. US AGENT & CONTACT PERSON INFORMATION

US agent & contact person name	Manoj Zacharias
Address	Liberty Management Group Ltd. 2871, Coastal Dr. Aurora, IL-60503, USA.
Phone	(630) 270-2921
Fax	(815) 986-2632
E-mail	manoj@libertymanagement.us

C. DEVICE IDENTIFICATION

Common Name	Surgeon's Gloves
Device Name	Surgeon's Gloves powder free
Product proprietary or trade name	JR MEDIC LATEX SURGEON'S GLOVES STERILE POWDER FREE

Classification name	Surgeon's Gloves
Device Classification	I
Product Code	KGO
Regulation Number	21 CFR 878.4460
Review Panel	General Hospital

D.PREDICATE DEVICE INFORMATION

Device	Name of device	510k Number	510K Owner
Predicate device	Pristeen Latex Surgeon's Gloves powder free with protein content labeling claim of 50 µg/dm² or less per glove of extractable protein	K172942	Beta Healthcare Products Pvt.Ltd, Plot No 21B, Cochin Special Econmic Zone, Kakkanad,Kerala, India-682037.
Reference device	Medismart+ Latex Surgeon's Gloves powder 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, JR Medic Latex Surgeon's Gloves Sterile 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), Standard Specification for Rubber Surgical Gloves.

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 using Gamma irradiation method to achieve the Sterility Assurance Level (SAL) of $10^{-6}$and place in a sterility maintained 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 CHARACTERISTIC COMPARISON TABLE

a. General Characteristics Comparison

Characteristic	Subject device K192328	Predicate device K172942	comparison
Product Code	KGO	KGO	Same
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	Same
Class	I	I	Same
Intended 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.	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.	Similar

Powdered or Powder free	powered free	powered free	Same
Compounding Classification	Type I - gloves compounded primarily from natural rubber latex	Type I - gloves compounded primarily from natural rubber latex	Same
Sterilization	Radiation, SAL- 10^{-6}	ETO/as well as Radiation, SAL- 10^{-6}	Different
Labeling	Meet FDA's label Requirements	Meet FDA's label Requirements	Same
Special label claim	Protein content labeling claim of 50 µg/dm² or less	Protein content labeling claim of 50 µg/dm² or less	Same
Type of use	Over the counter use	Over the counter use	Same

b. Technological Characteristics Comparison

Specification and physical properties per ASTM D3577- 09(Reapproved 2015), Standard Specification for Rubber Surgical Gloves.		Subject device K192328	Predicate device K172942	Remarks
Dimensions Length: Min 265 mm		300 mm	282 mm	Similar
Width				
Size	6.0(76+/-6mm) 6.5(83+/-6mm) 7.0(89+/-6mm) 7.5(95+/-6mm) 8.0(102+/-6mm) 8.5(108+/-6mm) 9(114+/-6mm)	78mm 85mm 88mm 97mm 103mm 110mm 116mm	78mm 84mm 91mm 97mm 103mm 109mm 115mm	Similar
Thickness for all sizes				
Cuff, Palm, Finger Tip Min 0.10 mm		Cuff- 0.11mm Palm- 0.18mm Finger Tip- 0.21mm	Cuff- 0.13mm Palm-0.16mm Finger Tip- 0.18mm	Similar
Physical Properties Before Ageing –for all sizes				
Tensile Strength 24Mpa minimum		26.0Mpa	28.0Mpa	Similar
Ultimate Elongation 750% minimum		860%	920%	
Stress at 500% 5.5 MPa Max		2.7 Mpa	3 Mpa	
Physical Properties After Ageing –for all sizes				
Tensile Strength 18Mpa minimum		22.0Mpa	24.0Mpa	Similar
Ultimate Elongation 560% minimum		725%	750%	
Freedom from Holes AQL 1.5, AST M D5151-06, (2015), Standard Test Method for Detection of Holes		AQL 1.0	AQL 1.0	Similar

in Medical Gloves			
Powder content < 2 mg/Glove, ASTM D6124-06, (2017), Standard Test Method for Residual Powder on Medical Gloves	0.34 mg/Glove	0.3 mg/glove	Similar
Protein Content < 50 µg/ dm^2, 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	43 µg/ dm^2	40 µg/ dm^2	Similar
Biocompatibility			
ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Non- irritant and Non-Sensitizer	Non- irritant and Non-Sensitizer	Same
ISO 10993-5: 2009 (E), Biological Evaluation of Medical Devices - Part 5-Tests for in vitro Cytotoxicity	Cytotoxic	Non cytotoxic	Different
ISO 10993-11: 2017(E). Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity,	No systemic toxicity under the conditions of the test	Not tested	Different
USP 41 <151> Pyrogen Test	Non pyrogenic	Non pyrogenic	same

H. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

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

Sl.No	Criteria	Specification as per ASTMD3577-09, Standard Specification for Rubber Surgical Gloves	Average value of subject device	Compliance with the ASTMD 3577-09, Standard Specification for Rubber Surgical Gloves
1	Length			
	Size 6	Min 265mm	306mm	Yes
	Size 6'/2	Min 265mm	306mm	Yes
	Size 7	Min 265mm	305mm	Yes
	Size 7'/2	Min 265mm	305mm	Yes
	Size 8	Min 265mm	305mm	Yes
	Size 8'/2	Min 265mm	305mm	Yes
	Size 9	Min 265mm	305mm	Yes

2	Width			
	Size 6	76+/-6mm	78mm	Yes
	Size 6'/2	83+/-6mm	85mm	Yes
	Size 7	89+/-6mm	88mm	Yes
	Size 7'/2	95+/-6mm	97mm	Yes
	Size 8	102+/-6mm	103mm	Yes
	Size 8'/2	108+/-6mm	110mm	Yes
	Size 9	114+/-6mm	116mm	Yes
3	Finger Thickness (All sizes)	Min 0.10mm	0.21mm	Yes
4	Palm Thickness (All sizes)	Min 0.10mm	0.18mm	Yes
5	Cuff Thickness (All sizes)	Min 0.10mm	0.11mm	Yes

SL.NO	Criteria	Specification as per ASTMD3577-09 Standard Specification for Rubber Surgical Gloves	Average value of subject device	Whether subject device complied with the ASTMD3577 -09, Standard Specification for Rubber Surgical Gloves
6	Tensile Strength			
	Before aging (All sizes)	24Mpa minimum	26.0Mpa	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	18Mpa minimum	22.0Mpa	Yes
7	Ultimate Elongation			
	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	2.7 Mpa	Yes
9	Pinhole AQL			
	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

Bench tests were conducted to verify that the proposed device met all design specifications or acceptance criteria found in the test method or standard. The test results demonstrated that the proposed device met design specifications or acceptance criteria with the following standards:

ASTM D3577-09(15):- 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 10993-11:2017(E) Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity and Biological Tests
USP 41 <151> Pyrogen Test
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

I. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that, JR MEDIC Latex Surgeon's Gloves Sterile Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicated device K172942.