December 27, 2021

Pentavest Holdings Sdn Bhd
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE114
Aurora, Illinois 60504

Re: K212848
Trade/Device Name: Sterile Latex Surgical Gloves Powder Free
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: September 1, 2021
Received: September 7, 2021

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,

Clarence W. Murray III -S

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)*
K212848

Device Name

Sterile Latex Surgical Gloves powder free

Indications for Use *(Describe)*

Sterile Latex Surgical Gloves Powder Free 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.

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K212848
510K SUMMARY
As required by: 21CFR § 807.92

A. APPLICANT INFORMATION

1.	Submitter Name	Pentavest Holdings Sdn Bhd
2	Date Submitted	01 September 2021
3	Address	No. 9574-9578, Jalan PTB 2 , Kawasan Perindustrian Tangga, Batu , 76400 Melaka, Malaysia
4	Phone	+601 22332689
5	Fax	------
6	E-mail	bjteng@pentavest.com.my
7	Contact Person	Teng Boon Joo
8	Designation	Managing Director
9	Contact Number	+601 22332689
10	Contact Email	bjteng@pentavest.com.my

B. US AGENT & CONTACT PERSON INFORMATION

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

C. DEVICE IDENTIFICATION

16	Common Name	Surgical Gloves
17	Device Name	Sterile Latex Surgical Gloves Powder Free
	Product proprietary or trade name	**George Glove**
18	Classification name	Surgeon's Gloves
19	Device Classification	1
20	Product Code	KGO
21	Regulation Number	21 CFR 878.4460
22	Review Panel	Gen & Plastic Surgery

D. PREDICATE DEVICE INFORMATION

Description	Name of device	510k Number	510K Owner
Predicate device	JR Medic Latex Surgeon's Gloves Sterile Powder Free with protein content labeling claim of 50 µg/ dm^2 or less per glove of extractable protein	K192328	***JR Engineering & Medical Technologies (M) SDN. BHD.*** Lot 8 &10, Jalan Zurah 3 & Lot 1&3, Jalan Zurah 3A/1, Pusat Perindustrian 2, 44200 Rasa, Hulu Selangor, Selangor Darul Ehsan, Malaysia.

E. DESCRIPTION OF THE DEVICE

The proposed device, Sterile Latex Surgical Gloves Powder Free with protein content labeling claim of 50 µg/ dm^2 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 D3577-2019, Standard Specification for Rubber Surgical Gloves.

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

The proposed device is Sterile Latex Surgical Gloves Powder Free, and variants of different sizes.

All variants share the same natural color (No color is added).

The proposed device is sterilized using Gamma Radiation 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 Sterile Latex Surgical Gloves Powder Free 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

a. General Characteristics Comparison

Characteristic	Subject device K212848	Predicate device K192328	Remarks
Product Code	KGO	KGO	Same
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	Same
Class	1	1	Same
Intended Use	A Sterile Latex Surgical Gloves Powder Free 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	Powder free	Powder free	Same
Classification as per ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves	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}	Similar
Label and Labeling	Meet FDA's label Requirements	Meet FDA's label Requirements	Same
Special label claim	Protein content labeling claim of 50µg/dm² or less per glove of extractable protein for Latex Surgeon's Gloves Powder Free.	Protein content labeling claim of 50µg/dm² or less per glove of extractable protein for Latex Surgeon's Gloves Powder Free.	Same
Type of use	Over the counter use	Over the counter use	Same

b. Technological Characteristics Comparison

Characteristics	Acceptance criteria of the standard		Remarks
	Subject device K212848	**Predicate device K192328**	
Dimensions **Length**:- Min 265 mm	380 mm	300 mm	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
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) 9.0 (114+/6mm)	 74mm 86mm 92mm 98mm 105mm 110mm 116mm	 78mm 85mm 88mm 97mm 103mm 110mm 116mm	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Cuff, Palm, Finger Tip Min 0.10 mm	Cuff-0.12mm Palm-0.16mm Finger Tip-0.21mm	Cuff-0.11mm Palm-0.18mm Finger Tip-0.21mm	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Tensile Strength 24Mpa minimum	28.55Mpa	26.0Mpa	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Ultimate Elongation 750% minimum	870%	860%	
Stress at 500% 5.5 MPa Max	5.1Mpa	2.7 Mpa	
Tensile Strength 18Mpa minimum	23.48Mpa	22.0Mpa	Similar Meets ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves
Ultimate Elongation 560% minimum	731%	725%	

Characteristics	Acceptance criteria of the standard		Remarks
	Subject device K212848	**Predicate device K192328**	
Freedom from Holes AQL 1.5	AQL 1.0	AQL 1.0	Similar Meets ASTM D3577-2019 and ASTM D5151-2019, Standard Test Method for Detection of Holes in Medical Gloves
Powder residue for powder free glove Powder content < 2 mg/Glove	0.40 mg/Glove	0.34 mg/Glove	Similar Meets ASTM D3577-2019 and ASTM D6124-06,(Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
Protein Content ≤50 µg/ dm^2	50 µg/ dm^2	43µg/ dm^2	Similar Meets ASTM D3577-2019, ASTM D5712-15, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method

Characteristics	Acceptance criteria of the standard			Remarks
	Biocompatibility	Subject device K212848	Predicate device K192328	
Skin Irritation & Skin Sensitization	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
In vitro cytotoxicity	ISO 10993-5:2009(E),Biological Evaluation of Medical Devices - Part 5-Tests for in vitro Cytotoxicity	Cytotoxic	Cytotoxic	Same
Material Mediated pyrogenicity	ISO 10993-11:2017(E) ,Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity and USP 41 <151>Pyrogen Test	-----	Non pyrogenic	-----
Systemic Toxicity	ISO 10993-11:2017(E) ,Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity	Under the conditions of study the device extracts do not pose a systemic toxicity concern	No data available	----
Bacterial Endotoxin	USP 42 <85>	<20EU/pair of gloves	No data available	----

H. PRODUCT COMPARISON IN COMPLIANCE WITH ASTM D 3577-09,STANDARD SPECIFICATION FOR RUBBER SURGICAL GLOVES

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

Sl.No	Criteria	Specification as per ASTM D3577-2019, Standard Specification for Rubber Surgical Gloves	Average value of subject device	Whether subject device complied with the ASTM D3577- 2019, Standard Specification for Rubber Surgical Gloves
1	**Length**			
	Size 6	Min 265mm	383mm	Yes
	Size 6'/2	Min 265mm	385mm	Yes
	Size 7	Min 265mm	388mm	Yes
	Size 7'/2	Min 265mm	390mm	Yes
	Size 8	Min 265mm	392mm	Yes
	Size 8'/2	Min 265mm	394mm	Yes
	Size 9	Min 265mm	396mm	Yes
2	**Width**			
	Size 6	76+/-6mm	74mm	Yes
	Size 6'/2	83+/-6mm	86mm	Yes
	Size 7	89+/-6mm	92mm	Yes
	Size 7'/2	95+/-6mm	98mm	Yes
	Size 8	102+/-6mm	105mm	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	0.16mm	Yes
5	Cuff Thickness (All sizes)	Min 0.10mm	0.12mm	Yes

SL.NO	CRITERIA	Specification as per ASTM D3577-2019 Standard Specification for Rubber Surgical Gloves	Average Value of Subject Device	Whether Subject Device Complied with the ASTM D3577 - 2019 Standard Specification for Rubber Surgical Gloves
6	**Tensile Strength**			
	Before aging (All sizes)	24Mpa minimum	28.55Mpa	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	18Mpa minimum	23.48Mpa	Yes
7	**Ultimate Elongation**			
	Before aging (All sizes)	750% minimum	870%	Yes
	After aging@ 70°±2C for 166±2 hr (All sizes)	560% minimum	731%	Yes
8	Stress at 500% before ageing (All sizes)	5.5 MPa Max	5.1 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

I. NON-CLINICAL TEST CONCLUSION

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

ASTM D3577-2019:- Standard Specification for Rubber Surgical Gloves.

ASTM D5151-2019:- 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 F1929-2015:- 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 10993-5:2009(E) Biological Evaluation of Medical Devices - Part 5-Tests for in vitro Cytotoxicity

ISO 10993-11:2017(E) Biological Evaluation of Medical Devices - Part 11- Tests for Systemic Toxicity and Biological Tests

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

USP 42 <85> Bacterial Endotoxin Test

Test Methodology/Standard	Purpose	Acceptance Criteria	Results
ISO 10993-10 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
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
USP 42 <85>	Bacterial Endotoxin Test	<20EU/pair of gloves	<20EU/pair of gloves

J. SUMMARY OF CLINICAL TESTING

Clinical data was not required for this submission.

K. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission Sterile Latex Surgical Gloves Powder Free is as safe, as effective, and performs as well as the legally marketed predicated device K192328, JR MEDIC Latex Surgeon's Gloves Sterile Powder Free.