September 16, 2021

Aspen Glove Sdn. Bhd.
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114
Aurora, Illinois 60504

Re: K211478
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: August 16, 2021
Received: August 16, 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, 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)*
K211478

Device Name

Sterile Latex Surgical Gloves powder free

Indications for Use *(Describe)*

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.

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
K211478
As required by: 21CFR § 807.92

A. APPLICANT INFORMATION

1.	Submitter Name	Aspen Glove Sdn. Bhd.
2	Date Submitted	14 September 2021
3	Address	Aspen House, 300, JLN Macalister, 10450 Georgetown, Pulau Pinang, Malaysia
4	Phone	+604- 227 5000
5	Fax	+604- 227 5000
6	E-mail	corporate@aspen.com.my
7	Contact Person	Mr. Iskandar Basha bin Abdul Kadir
8	Designation	Managing Director
9	Contact Number	017 -550 0577
10	Contact Email	Iskandar@aspenglove.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	Surgeon's Gloves
17	Device Name	Sterile Latex Surgical Gloves Powder Free
	Product proprietary or trade name	**AspenMed+S**
18	Classification name	Surgeon's Gloves
19	Device Classification	1
20	Product Code	KGO
21	Regulation Number	21 CFR 878.4460
22	Regulation Name	Non-Powdered Surgeon's Glove
23	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 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 -09(2015), 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 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 TABLE

a. General Characteristics Comparison

Characteristic	Subject device K211478	Predicate device K192328	Comparison
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 ASTMD3577-09, 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}	Radiation, SAL- 10^{-6}	Same
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

Sl. No	Criteria	Specification as per ASTMD 3577-09, Standard Specification for Rubber Surgical Gloves	Subject device K211478	Predicate device K192328	Comparison
1	**Length**				
	Size 6	Min 265mm	385mm	306mm	Similar **Meets ASTM D3577-09(Reapproved 2015), Standard Specification for Rubber Surgical Gloves**
	Size 6'/2	Min 265mm	386mm	306mm	
	Size 7	Min 265mm	388mm	305mm	
	Size 7'/2	Min 265mm	390mm	305mm	
	Size 8	Min 265mm	392mm	305mm	
	Size 8'/2	Min 265mm	394mm	305mm	
	Size 9	Min 265mm	396mm	305mm	
2	**Width**				
	Size 6	76+/-6mm	74mm	78mm	Similar **Meets ASTM D3577-09(Reapproved 2015), Standard Specification for Rubber Surgical Gloves**
	Size 6'/2	83+/-6mm	86mm	85mm	
	Size 7	89+/-6mm	92mm	88mm	
	Size 7'/2	95+/-6mm	98mm	97mm	
	Size 8	102+/-6mm	103mm	103mm	
	Size 8'/2	108+/-6mm	110mm	110mm	
	Size 9	114+/-6mm	116mm	116mm	
3	Finger Thickness (All sizes)	Min 0.10mm	0.20mm	0.21mm	Similar **Meets ASTM D3577-09(Reapproved 2015), Standard Specification for Rubber Surgical Gloves**
4	Palm Thickness (All sizes)	Min 0.10mm	0.15mm	0.18mm	
5	Cuff Thickness (All sizes)	Min 0.10mm	0.12mm	0.11mm	

Sl. No	Criteria	Specification as per ASTMD 3577-09, Standard Specification for Rubber Surgical Gloves	Average Value of Subject device K211478	Average Value of Predicate device K192328	Comparison
6	**Tensile Strength**				
	Before aging (All sizes)	24 Mpa minimum	28.55 Mpa	26.00 Mpa	Similar **Meets ASTM D3577-09(Reapproved 2015), Standard Specification for Rubber Surgical Gloves**
	After aging@ 70°±2C for 166±2 hr (All sizes)	18 Mpa minimum	23.48 Mpa	22.00 Mpa	
7	**Ultimate Elongation**				
	Before aging (All sizes)	750% minimum	870%	860%	Similar **Meets ASTM D3577-09 (Reapproved 2015), Standard Specification for Rubber Surgical Gloves**
	After aging@ 70°±2C for 166±2 hr (All sizes)	560% minimum	731%	725%	
8	Stress at 500% before ageing (All sizes)	5.5 MPa Max	5.1 Mpa	2.7 Mpa	
9	**Pinhole AQL**				
	Before aging (All sizes)	Max 1.5	1.0	1.0	Similar **Meets ASTM D3577-09 (15) and ASTM D5151-06, (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves**
	After aging@ 70°C for 7 days (All sizes)	Max 1.5	1.0	1.0	

Sl. No	Criteria	Specification as per ASTMD 3577-09, Standard Specification for Rubber Surgical Gloves	Average Value of Subject device K211478	Average Value of Predicate device K192328	Comparison
10	**Powder Content**				
	Powder residue for powder free glove (All sizes)	Powder content ≤ 2 mg/Glove	0.40 mg/Glove	0.34 mg/Glove	Similar **Meets ASTM D3577 and ASTM D6124-06,(Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves**
11	**Protein Content**				
	Protein Content	≤ 50 µg/ dm^2	38 µg/ dm^2	43 µg/ dm^2	Similar **Meets ASTM D3577, ASTM D5712-15, Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber**

c. Biocompatibility Comparison

Biocompatibility	Test Method	Subject device K211478	Predicate device K192328	Comparison
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

Biocompatibility	Test Method	Subject device K211478	Predicate device K192328	Comparison
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	Non pyrogenic	Same
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. NON-CLINICAL TESTING SUMMARY

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

PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D3577-09 (Reapproved 2015),	To determine the length of the gloves	Min 265 mm for all sizes	Size 6	385mm
			Size 6'/2	386mm

Standard Specification for Rubber Surgical Gloves			Size 7	388mm
			Size 7'/2	390mm
			Size 8	392mm
			Size 8'/2	394mm
			Size 9	396mm

Test Method	**Purpose**	**Acceptance Criteria**		**Result**
ASTM D3577-09 (Reapproved 2015), Standard Specification for Rubber Surgical Gloves	To determine the width of the gloves	Size 6	76+/-6mm	74mm
		Size 6'/2	83+/-6mm	86mm
		Size 7	89+/-6mm	92mm
		Size 7'/2	95+/-6mm	98mm
		Size 8	102+/-6mm	103mm
		Size 8'/2	108+/-6mm	110mm
		Size 9	114+/-6mm	116mm

Test Method	**Purpose**	**Acceptance Criteria**	**Result**		
			Size	**Palm**	**Finger**
ASTM D3577-09 (Reapproved 2015), Standard Specification for Rubber Surgical Gloves	To determine the thickness of the gloves	Palm 0.10 mm min Finger 0.10 mm min for all sizes	6	0.15mm	0.20mm
			6'/2	0.15mm	0.20mm
			7	0.15mm	0.20mm
			7'/2	0.15mm	0.20mm
			8	0.15mm	0.20mm
			8'/2	0.15mm	0.20mm
			9	0.15mm	0.20mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D3577-09 (Reapproved 2015), Standard Specification for Rubber Surgical Gloves	To Determine the physical properties- Tensile strength	**Before Ageing** 24Mpa Min for all sizes **After Ageing** 18Mpa Min for all sizes	**Size**	**Before Ageing**	**After Ageing**
			6	27.2Mpa	22.1Mpa
			6'/2	27.5Mpa	22.6Mpa
			7	28.3Mpa	23.4Mpa
			7'/2	28.5Mpa	23.6Mpa
			8	29.2Mpa	23.9Mpa
			8'/2	29.5Mpa	24.3Mpa
			9	29.7Mpa	24.5Mpa
	To Determine the physical properties- Ultimate Elongation	**Before Ageing** 750% Min for all sizes **After Ageing** 560% Min for all sizes	**Size**	**Before Ageing**	**After Ageing**
			6	864%	727%
			6'/2	867%	729%
			7	869%	730%
			7'/2	871%	731%
			8	872%	732%
			8'/2	873%	733%
			9	874%	734%

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 1.5	Gloves Passes AQL 1.0	
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2Mg/Glove Max	Size 6	0.26mg/glove
			Size 6'/2	0.29mg/glove
			Size 7	0.32mg/glove
			Size 7'/2	0.38mg/glove
			Size 8	0.44mg/glove
			Size 8'/2	0.52mg/glove
			Size 9	0.62mg/glove

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
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 the a conditions of study not 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 the conditions of 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	NMT 20 EU/pair of gloves	<20 EU/pair of gloves

Summary of clinical performance data.

Clinical data was not required for this submission.

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 or better than the legally marketed predicated device K192328, JR MEDIC Latex Surgeon's Gloves Sterile Powder Free.