September 20, 2021

Aspen Glove Sdn. Bhd.
% Manoj Zacharias
Consultant
Liberty Mangement Group Ltd.
75 Executive Dr. STE114
Aurora, Illinois 60504

Re: K211477
Trade/Device Name: Latex Examination Powder Free Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
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,

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

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)*
K211477

Device Name

Latex Examination Powder Free Gloves

Indications for Use *(Describe)*

Latex Examination Powder Free Gloves are 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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510K SUMMARY

As required by 21CFR§807.92(c)

A. APPLICANT INFORMATION

Applicant	Aspen Glove Sdn. Bhd.
Address	Aspen House, 300, JLN Macalister, 10450 Georgetown, Pulau Pinang, Malaysia
Phone	+604- 227 5000
Fax	+604- 227 5000
E-mail	corporate@aspen.com.my
Contact Person	Mr. Iskandar Basha bin Abdul Kadir
Designation	Managing Director
Contact Number	017 -550 0577
Contact Email	Iskandar@aspenglove.com.my
Date Submitted	APRIL 25th, 2021

B. DEVICE IDENTIFICATION

Name of the device	Latex Examination Powder Free Gloves
Product proprietary or trade name	**AspenPro+**
Common or usual name	Latex Examination Powder Free Gloves
Classification name	Patient Examination Gloves
Device Classification	Class I
Product Code	LYY
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Legally Marketed devices that Equivalency is claimed	JR Medic Powder free Latex Examination Gloves
510(K) Number	K192329
Regulatory Class	Class I
Product code	LYY

D. DESCRIPTION OF THE DEVICE:

Latex Examination Powder Free Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D3578-05 (Reapproved 2015), Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are natural in color (No color is added) and are powder free.

E. INDICATIONS FOR USE/INTENDED USE OF THE DEVICE:

Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

F. TECHNOLOGICAL CHARACTERISTICS

Characteristics	Standards	Device Performance			Comparison
		Predicate	Current		
510(K) Number	---	K192329	K211477		
Name of device	---	JR MEDIC Blue Latex Examination Powder Free Gloves	Latex Examination Powder Free Gloves		---
Dimensions-Length	ASTMD3578-05 (Reapproved 2015)	Length > 230 mm	Length > 230 mm		Similar
			Size	**Average**	
			X-Small	236	
			Small	236	
			Medium	242	
			Large	248	
			X-Large	252	
Dimensions- Width	ASTMD3578-05 (Reapproved 2015)	Width Min 95+/-10 mm (for medium size)	Width Min 95+/-10 mm (for medium size)		Similar
			Size	**Average**	
			X-Small	76	
			Small	85	
			Medium	98	
			Large	106	
			X-Large	116	
Physical Properties-Tensile Strength	ASTMD3578-05 (Reapproved 2015)	<u>Before Ageing</u> Tensile Strength > 18 Mpa	<u>Before Ageing</u> Tensile Strength > 18 Mpa		Similar
			Size	Actual value	
			X-Small	22.08	
			Small	22.16	
			Medium	22.22	
			Large	22.30	
			X-Large	22.32	
		<u>After Ageing</u> Tensile Strength > 14 Mpa	<u>After Ageing</u> Tensile Strength > 14 Mpa		Similar
			Size	Actual value	
			X-Small	18.50	
			Small	18.56	
			Medium	18.65	
			Large	18.74	
			X-Large	18.76	

<table>
<tr><th>Characteristics</th><th>Standards</th><th colspan="2">Device Performance</th><th>Comparison</th></tr>
<tr><th></th><th></th><th>Predicate</th><th>Current</th><th></th></tr>
<tr><td>510(K) Number</td><td></td><td>K192329</td><td></td><td></td></tr>
<tr><td rowspan="12">Physical Properties-Ultimate Elongation</td><td rowspan="12">ASTMD3578-05 (Reapproved 2015)</td><td rowspan="12">Before Ageing
Ultimate Elongation > 650%

After Ageing
Ultimate Elongation >500%</td><td><u>Before Ageing</u>
Ultimate Elongation > 650%</td><td rowspan="12">Similar</td></tr>
<tr><td>Size | Actual value</td></tr>
<tr><td>X-Small | 856</td></tr>
<tr><td>Small | 868</td></tr>
<tr><td>Medium | 874</td></tr>
<tr><td>Large | 880</td></tr>
<tr><td>X-Large | 882</td></tr>
<tr><td>After Ageing
Ultimate Elongation > 500%</td></tr>
<tr><td>Size | Actual value</td></tr>
<tr><td>X-Small | 842</td></tr>
<tr><td>Small | 850</td></tr>
<tr><td>Medium | 855</td></tr>
<tr><td>Large | 860</td></tr>
<tr><td>X-Large | 862</td></tr>
<tr><td rowspan="6">Thickness</td><td rowspan="6">ASTMD3578-05 (Reapproved 2015)</td><td rowspan="6">Palm > 0.08 mm
Finger > 0.08 mm</td><td>Palm > 0.08 mm
Finger > 0.08 mm</td><td rowspan="6">Similar</td></tr>
<tr><td>Size | Palm (Actual value) | Finger (Actual value)</td></tr>
<tr><td>X-Small | 0.12 | 0.14</td></tr>
<tr><td>Small | 0.12 | 0.14</td></tr>
<tr><td>Medium | 0.12 | 0.14</td></tr>
<tr><td>Large | 0.12 | 0.14</td></tr>
<tr><td>X-Large | 0.12 | 0.14</td></tr>
<tr><td rowspan="7">Powder Free Residue</td><td rowspan="7">ASTMDD 3578-10 (Reapproved 2015)</td><td rowspan="7">≤2 mg/glove</td><td>≤2 mg/glove</td><td rowspan="7">Similar</td></tr>
<tr><td>Size | Residual powder content (mg/glove)</td></tr>
<tr><td>X-Small | 0.21</td></tr>
<tr><td>Small | 0.21</td></tr>
<tr><td>Medium | 0.22</td></tr>
<tr><td>Large | 0.22</td></tr>
<tr><td>X-Large | 0.22</td></tr>
<tr><td rowspan="4">Biocompatibility</td><td>Primary Skin Irritation-ISO 10993-10:2010(E)</td><td>Under the condition of study, not an irritant</td><td colspan="2">Under the condition of study not an irritant</td><td>Same</td></tr>
<tr><td>Dermal Sensitization-ISO 10993-10:2010(E)</td><td>Under the conditions of the study, not a sensitizer</td><td colspan="2">Under the conditions of the study, not a sensitizer</td><td>Same</td></tr>
<tr><td>In vitro cytotoxicity ISO10993-5 :2009(E)</td><td>Under the conditions of the study, non-cytotoxic</td><td colspan="2">Under the conditions of the study, non-cytotoxic</td><td>Same</td></tr>
<tr><td>Material mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151></td><td>Under the conditions of the study non pyrogenic</td><td colspan="2">Under the conditions of the study, non-pyrogenic</td><td>Same</td></tr>
</table>

Characteristics	Standards	Device Performance		Comparison
		Predicate	Current	
510(K) Number		K192329		
Biocompatibility	Bacterial Endotoxin test USP 42<85>	No data available	<20EU/pair of gloves	-----
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the condition of study not systemic toxic	Under the conditions of study the device extracts do not pose a systemic toxicity concern	same
Water Tight (1000 ml)	ASTM D5151-06 (Reapproved 2015)	Passes AQL-1.5	Passes AQL-1.5	Same
Intended use		JR MEDIC Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	-	Natural Latex	Natural Latex	Identical
Color	-	Blue	Natural (No color is added)	different
Texture	-	Finger Texture	Finger texture	Identical
Size	ASTMD 3578-5 (Reapproved 2015)	Small, Medium, Large & X Large	X Small, Small, Medium, Large, X-Large	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non Sterile	Non Sterile	Same
Powder/Powder free	-	Powder free	Powder free	Same
Label and Labeling	FDA Label requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD.	Aspen Glove Sdn. Bhd.	---

G. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	X-Small 236 mm Small 236 mm Medium 242 mm Large 248 mm X-Large 252 mm
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	X-Small 70+/-10 mm Small 80+/-10mm Medium 95+/-10 mm Large 111+/-10 mm X-Large 115+/-10 mm	X-Small 76 mm Small 85 mm Medium 98 mm Large 106 mm X-Large 116 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To determine the thickness of the gloves	Palm 0.08 mm min Finger 0.08 mm min for all sizes	**Size** X-Small Small Medium Large X-Large	**Palm** 0.12mm 0.12mm 0.12mm 0.12mm 0.12mm	**Finger** 0.14mm 0.14mm 0.14mm 0.14mm 0.14mm
ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 18Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 22.08 Mpa 22.16 Mpa 22.22 Mpa 22.30 Mpa 22.32 Mpa	**After ageing** 18.50 Mpa 18.56 Mpa 18.65 Mpa 18.74 Mpa 18.76 Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 650% Min for all sizes **After Ageing** Ultimate Elongation 500% Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 856% 868% 874% 880% 882%	**After ageing** 842% 850% 855% 860% 862%
	To Determine the physical properties-stress at 500% Elongation	**Before Ageing** 5.5 Mpa Max for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 5.1 Mpa 5.1 Mpa 5.2 Mpa 5.2 Mpa 5.2 Mpa	**NA**
ASTM D5151-06 (Reapproved 2015) 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	**Size** X-Small Small Medium Large X-Large	**Residual Powder Content** 0.21 mg/glove 0.21 mg/glove 0.22 mg/glove 0.22 mg/glove 0.22 mg/glove	
ASTM D5712-95 (Re approved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber	To determine the extractable protein in the gloves.	200 µg/ dm² Max for all sizes	**Size** X-Small Small Medium Large X-Large	**Extractable Protein content** 32 µg/ dm² 32 µg/ dm² 32 µg/ dm² 32 µg/ dm² 32 µg/ dm²	

The performance test data of the non-clinical tests meet following standards:

- ASTM D3578-05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves
- ASTM D5151-06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5712-95 (Reapproved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber

H. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission Latex Examination Powder Free Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device *K192329*.