September 16, 2021

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

Re: K211479
Trade/Device Name: Blue Nitrile Examination Glove Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
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)*
K211479

Device Name

Blue Nitrile Examination Glove Powder Free

Indications for Use *(Describe)*

Blue Nitrile Examination Gloves Powder Free is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
K211479
As required by: 21CFR§807.92(c)

A. APPLICANT INFORMATION

510(K) Owner's Name	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	16 September 2021

B. DEVICE IDENTIFICATION

Name of the device	Blue Nitrile Examination Glove Powder Free
Product proprietary or trade name	**AspenMed+**
Common or usual name	Exam Gloves
Classification name	Patient Examination Gloves
Device Classification	Class-I
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	JR Engineering & Medical Technologies (M) SDN.BHD.
510(K) Number	K192333
Regulatory Class	I
Product code	LZA

D. DESCRIPTION OF THEDEVICE:

Blue Nitrile Examination Gloves Powder Free are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are blue in color and are powder free.

E. INTENDED USE OF THE DEVICE:

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

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristics	Standards	Device Performance		Remarks
		Predicate	Subject	
510(K) Number		**K192333**	**K211479**	----
Name of device		JR MEDIC Blue Nitrile Examination Gloves Powder-free	Blue Nitrile Examination Gloves Powder Free	----
Dimensions	ASTMD6319-10 (Reapproved 2015)	Length Min 230 m Width Min 95+/-10 mm(for medium size)	Length Min 230 mm Width Min 95+/-10 mm(for medium size)	Same
Physical Properties	ASTMD6319-10 (Reapproved 2015)	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Same
Thickness	ASTMD6319-10 (Reapproved 2015)	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Residue	ASTMD6319-10	≤2 mg/glove	≤2 mg/glove	Similar
Biocompatibility	Primary Skin Irritation- ISO 10993-10:2010(E)	Under the condition of study not an irritant	Under the condition of study not an irritant	Same
	Dermal Sensitization- ISO 10993-10:2010(E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	Under the conditions of the study, cytotoxic	Under the conditions of the study, cytotoxic	Same
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	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	Same
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	Under the conditions of the study non pyrogenic	Under the conditions of the study non pyrogenic	Same
	Bacterial Endotoxin test USP 42<85>	No data available	<20EU/pair of gloves	-----

Characteristics	Standards	Device Performance		Remarks
		Predicate K192333	Current K211479	
Water Tight (1000 ml)	ASTM D5151-06	Passes AQL-1.5	Passes AQL-1.5	Similar
Intended use		JR MEDIC Blue Nitrile Examination Gloves Powder-free is disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Blue Nitrile Examination Gloves Powder free is disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Similar
Material	ASTMD 6319-10 (Reapproved 2015)	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger Texture	Same
Size	ASTMD 6319-10 (Reapproved 2015)	Extra Small, Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	Aspen Glove Sdn. Bhd. Malaysia	------

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standard D6319-10(Reapproved 2015).

NON-CLINICAL TESTING SUMMARY

PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes	X-Small:- 245 mm Small:- 245 mm Medium:- 246 mm Large:- 248 mm X-Large:- 248 mm
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	X-small:- 70+/-10 mm Small:- 80+/-10 mm Medium:- 95+/-10mm Large:- 110+/-10 mm X-Large:- 120+/-10 mm	X-small- 68 mm Small:- 80 mm Medium:- 92 mm Large:- 105 mm X-Large:- 115 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	Size X-Small Small Medium Large X-Large	Palm 0.09mm 0.09mm 0.09mm 0.09mm 0.09mm	Finger 0.15mm 0.15mm 0.15mm 0.15mm 0.15mm
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 18.45Mpa 18.54Mpa 18.62Mpa 18.67Mpa 18.72Mpa	**After ageing** 17.54Mpa 17.56Mpa 17.68Mpa 17.75Mpa 17.80Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% Min for all sizes **After Ageing** Ultimate Elongation 400% Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before ageing** 686% 690% 694% 702% 705%	**After ageing** 659% 665% 668% 670% 674%

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 1.5	
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** 0.21mg/glove 0.21mg/glove 0.22 mg/glove 0.22 mg/glove 0.22 mg/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 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
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

G. Clinical Testing Summary

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(K) process.

H. CONCLUSION

The conclusions drawn from the non clinical test demonstrate that the subject device in 510(K) submission, Blue Nitrile Examination Gloves Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192333.