December 20, 2021

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

Re: K213076
Trade/Device Name: Blue Nitrile Examination Gloves Powder Free Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: September 18, 2021
Received: September 23, 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)*
K213076

Device Name

Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs

Indications for Use *(Describe)*

Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	Minimum Breakthrough Detection Time
Carmustine (BCNU) (3.3 mg/ml)	34.3 Minutes
Carboplatin (10 mg/ml)	>240 Minutes
Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	87.3 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 34.3 Minutes
Thiotepa (10 mg/ml) 87.3 Minutes

Warning: Do not use with Carmustine or Thiotepa.

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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K213076
510(K) SUMMARY
As required by: 21CFR§807.92(c)

A. APPLICANTINFORMATION

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	18 September 2021

B. DEVICE IDENTIFICATION

Name of the device	Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs
Product proprietary or trade name	**AspenMed+**
Common or usual name	Exam Gloves
Classification name	Patient Examination Gloves, Specialty
Device Classification	Class- I
Product Code	LZA, LZC
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for use with Chemotherapy Drugs)
510(K) Number	K210944
Regulatory Class	I
Product code	LZA, LZC, OPJ

D. DESCRIPTION OF THEDEVICE:

The subject device in 510(K) notification is a blue nitrile examination gloves powder free tested for use with Chemotherapy drugs.

The subject device is a patient examination glove made from acrylonitrile-butadiene copolymer dispersion, blue color, powder free and non sterile (as per 21CFR 880.6250, class I).

The subject device meets all the current specifications listed under the ASTM Specification D 6319 -2019, Standard Specification for Nitrile Examination Gloves for Medical Application. This device also complies with requirements for standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs as per ASTM D6978- 05(2019)

E. INTENDED USE OF THE DEVICE:

Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	**Minimum Breakthrough Detection Time (Minutes)**
Carmustine (BCNU) (3.3 mg/ml)	34.3 Minutes
Carboplatin (10 mg/ml)	>240 Minutes
Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	87.3 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 34.3 Minutes
Thiotepa (10 mg/ml) 87.3 Minutes

Warning: Do not use with Carmustine (BCNU) & Thiotepa

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

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE	PROPOSED DEVICE	
510(K) Number	-	**K210944**	**K213076**	
Name of device		Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for use with Chemotherapy Drugs)	Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs	Similar
Product Code	-	LZA, LZC, OPJ	LZA, LZC	Similar
Intended use		Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for use with Chemotherapy Drugs) disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. The proposed device was tested for use with chemotherapy drugs as per ASTM D6978-05 (2019), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.	Similar

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE K210944	PROPOSED DEVICE	
Regulation Number	-	21 CFR 880.6250	21 CFR 880.6250	Same
Material	-	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger texture	Same
Size	ASTM D6319-2019	Small, Large Medium, Large, Extra	Small, Medium, Large, Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	Same
Dimensions	ASTM D6319-2019	Length: Small- Min 220 mm & Medium, Large & Extra large- Min 230 mm Width Min 95+/-10 mm(Medium Size)	Length > 230 mm Width Min 95+/-10 mm(for medium size)	Similar
Physical Properties	ASTM D6319-2019	**Before Ageing** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Ageing** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	**Before Ageing** Tensile Strength > 14 Mpa Ultimate Elongation >500% **After Ageing** Tensile Strength >14 Mpa Ultimate Elongation > 400%	Same
Thickness	ASTM D6319-2019	Palm min 0.05 mm Finger min 0.05 mm	Palm >0.05 mm Finger > 0.05 mm	Same
Powder Free Residue	ASTM D6319-2019	≤2 mg/glove	≤2 mg/glove	Same
Watertight (1000 ml)	ASTM D5151-2019	Passes AQL-2.5	Passes AQL-1.5	Similar
Label and Labeling	FDA Label requirements	Meets FDA's requirements	Meets FDA's requirements	Same

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE K210944	PROPOSED DEVICE	
Bio-compatibility	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, potentially cytotoxic	Under the conditions of the study, cytotoxic	Similar
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	No Data Available	Under the conditions of the study non pyrogenic	----
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal	Under the condition of study does not induce any systemic toxic concern	Similar
	Bacterial Endotoxin test USP 42<85>	No data available	<20EU/pair of gloves	-----

Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978-05 (2019)

Busulfan (6mg/ml)	>240 Minutes	Not Tested	Different
Carmustine (BCNU) (3.3 mg/ml)	14.5 Minutes	34.3 Minutes	Different
Carboplatin (10 mg/ml)	>240 Minutes	>240 Minutes	Same
Cisplatin (1 mg/ml)	>240 Minutes	>240 Minutes	Same
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes	>240 Minutes	Same
Cytarabine (100 mg/ ml)	>240 Minutes	Not Tested	Different
Dacarbazine (10.0 mg/ml)	>240 Minutes	>240 Minutes	Same
Docetaxel (10 mg/ml)	>240 Minutes	Not Tested	Different
Doxorubicin HCl (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Etoposide (20 mg/ml)	>240 Minutes	>240 Minutes	Same
Fluorouracil (50 mg/ml)	>240 Minutes	>240 Minutes	Same
Ifosfamide (50 mg/ml)	>240 Minutes	>240 Minutes	Same
Mechlorethamine HCL (1 mg/ml)	>240 Minutes	Not Tested	Different
Methotrexate (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitomycin C (0.5 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitoxantrone (2 mg/ml)	>240 Minutes	>240 Minutes	Same
Paclitaxel (6 mg/ml)	>240 Minutes	>240 Minutes	Same
Thiotepa (10 mg/ml)	47.4 Minutes	87.3 Minutes	Different
Vincristine Sulfate (1 mg/ml)	>240 Minutes	>240 Minutes	Same

G. NON-CLINICAL TESTING SUMMARY PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 220 mm for Size Small & Min 230 mm for all other sizes	Small:- 245 mm Medium:- 246 mm Large:- 248 mm X-Large:- 248 mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Small:- 80+/-10 mm Medium:- 95+/-10 mm Large:- 110+/-10 mm X-Large:- 120+/-10 mm	Small:- 80 mm Medium:- 92 mm Large:- 105 mm X-Large:- 115 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-2019 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 Small Medium Large X-Large	Palm 0.09 mm 0.09 mm 0.09 mm 0.09 mm	Finger 0.15mm 0.15mm 0.15mm 0.15mm
ASTM D6319-2019 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** Small Medium Large X-Large	**Before ageing** 18.52 Mpa 18.61 Mpa 18.67 Mpa 18.72 Mpa	**After ageing** 17.54 Mpa 17.68 Mpa 17.74 Mpa 17.80 Mpa
	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** Small Medium Large X-Large	**Before ageing** 690% 693% 702% 705%	**After ageing** 665% 667% 669% 673%

Test Method	Purpose	Acceptance Criteria	Result	
ASTM D5151-2019 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** Small Medium Large X-Large	**Residual Powder Content** 0.21 mg/glove 0.22 mg/glove 0.22 mg/glove 0.22 mg/glove

H. 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.

I. Clinical Testing Summary

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

J. CONCLUSION

The conclusions drawn from the non clinical test demonstrate that the subject device in 510(K) submission, Blue Nitrile Examination Gloves Powder Free tested for use with Chemotherapy drugs is as safe, as effective, and performs as well as the legally marketed predicate device Harbour Health Powder Free Nitrile Examination Glove, Blue (Tested for use with Chemotherapy Drugs) K210944.