December 4, 2021

Mah Sing Healthcare Sdn Bhd
Azlan Hashim
Head, QA/RA
Wisma Mah Sing, Penthouse Suite 1, 163 Jalan Sungai Besi
Kuala Lumpur, Kuala Lumpur 57100
Malaysia

Re: K212535
Trade/Device Name: Nitrile Powder Free Blue Examination Gloves, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 23, 2021
Received: November 1, 2021

Dear Azlan Hashim:

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, 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)*
K212535

Device Name
Nitrile Powder Free Blue Examination Gloves, Non-Sterile

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger 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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Premarket Notification [510(k)] No: K212535

510 (K) SUMMARY

1.0 Device Name	Nitrile Powder Free Blue Examination Gloves, Non-Sterile
2.0 Submitter name / Contact details	Mah Sing Healthcare Sdn. Bhd Wisma Mah Sing, Penthouse Suite 1, 163 Jalan Sungai Besi, Kuala Lumpur 57100 **MALAYSIA** Contact Person Details: Mr. Azlan Hashim E-mail: azlan.hashim@mshealthcare.com Tel: +60-3-3396 2288, Extn: 2203 Fax: +60-3-3396 2299
3.0 Summary Preparation Date	December 3, 2021
4.0 Device Name & Classification	K2212535 Trade Name: Nitrile Powder Free Blue Examination Gloves, Non-sterile Classification Name: Polymer Patient Examination Glove Device Classification: I Regulation Number: 21 CFR 880.6250 Panel: General Hospital Product Code: LZA
5.0 Identification of The Legally Marketed Device	Predicate Device Name: Powder Free Nitrile Examination Gloves Predicate 510(K) Number: K210369 Manufacture's Name: Pastel Glove Sdn Bhd
6.0 Description of Device	Nitrile Powder Free Blue Examination Gloves, Non-Sterile are Class I patient examination gloves bearing the product code Nitrile – LZA (21CFR880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves without using any lubricant such as powder on the glove surface. These gloves are blue in color and are powder free. The gloves are ambidextrous single use disposable devices that come in four sizes (S, M, L and XL).

7.0 Indications for Use

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

8.0 Summary of the Technological Characteristic of the Device

Nitrile Powder Free Blue Examination Gloves, Non-sterile possesses the following technological characteristics (as compared to ASTM's or equivalent standards.
Summary of substantial equivalence is shown in Table 1 of this "510(k) Summary".

Non-clinical performance testing was performed to support a determination of substantial equivalence (refer to performance testing in Table 2) of this "510(k)" summary.
The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs in accordance with standards referenced.

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Table 1

Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
510(k) Number		K212535	K210369	-
Name of device		Nitrile Powder Free Blue Examination Gloves, Non-Sterile	Powder Free Nitrile Examination Gloves Non-Sterile	-
Product Code	-	LZA	LZA	Same product code
Intended Use	-	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same intended use
Classification	-	Class 1	Class 1	Same Class
Raw Rubber Material	ASTM D 6319-19	Nitrile (Acrylonitrile-butadiene)	Nitrile (Acrylonitrile-butadiene)	Same synthetic rubber material
Design, Colour and Surface Appearance	-	1. Ambidextrous 2. Blue 3. Powder free 4. Finger Textured	1. Ambidextrous 2. Blue 3. Powder free 4. Finger Textured	Same ambidextrous design, same colour, some features, and same textured area

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Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
Overall Length (Minimum 230mm)	ASTM D 6319-19	Average: 254 mm	Average: 242 mm	Similar
Width S: 75mm – 95mm M: 85mm – 105mm L: 100mm – 120mm XL:110mm – 130mm	ASTM D 6319-19	Average value: S: 86mm M: 96mm L: 107mm XL: 118mm	S: 84mm M: 94mm L: 103mm	Similar
Palm Thickness (Minimum 0.05mm)	ASTM D 6319-19	Average: 0.06mm	Average: 0.06mm	Similar
Finger Thickness (Minimum 0.05mm)	ASTM D 6319-19	Average: 0.09mm	Average: 0.08mm	Similar
Tensile Strength (Before aging) Minimum 14 MPa	ASTM D 6319-19	Average: 22.3MPa	Average: 17.75MPa	Similar
Tensile Strength (After accelerated aging) Minimum 14 MPa	ASTM D 6319-19	Average: 22.8MPa	Average: 16.07MPa	Similar
Ultimate Elongation (before aging) Minimum 500%	ASTM D 6319-19	Average: 526%	Average: 560%	Similar
Ultimate Elongation (after accelerated aging) Minimum 400%	ASTM D 6319-19	Average 531%	Average: 510%	Similar
Freedom of Holes Meet AQL 2.5 at G1	ASTM D 5151-19	Meet AQL 1.5 with G1	Meet AQL 1.5 with G1	Same
Residual powder test (Less than 2mg/glove)	ASTM D 6124-06	Average powder residue for each size. S: 0.36 mg /glove M: 0.32 mg /glove L: 0.36 mg /glove XL: 0.38 mg/glove	Average powder residue for each size. S: 0.45 mg /glove M: 0.43 mg /glove L: 0.27 mg /glove	Similar
Animal Irritation Test	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Similar
Dermal Sensitization	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer.	Similar
Cytotoxicity Test (MEM Elution Assay)	ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, cytotoxic.	Not done	Meeting the requirements per ISO 10993-5

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Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Not induce systemic toxicity	Not induce systemic toxicity	Similar
Expiration Date	ASTM D 7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves	3 years from date of manufactured	Not stated	-
Manufacturer	-	Mah Sing Healthcare Sdn Bhd	Pastel Glove Sdn Bhd	-

9.0 Summary of Non-Clinical Testing

Table 2 – Performance Testing

Non-Clinical Testing					
Test Method	**Purpose**	**Acceptance Criteria**		**Result**	
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.	To determine the residual powder in the gloves	Less than 2mg / glove		Size S Size M Size L Size XL	0.36mg /glove 0.32mg /glove 0.36mg /glove 0.38mg /glove
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.	To determine the holes in the gloves	Inspection level, G-I AQL 2.5 (In accordance with ASTM D6319-19)		Passed G-I, AQL 1.5	
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the length of the gloves	Size S Size M Size L Size XL	220mm, min 230mm, min 230mm, min 230mm, min	Size S Size M Size L Size XL	254mm, average 254mm, average 254mm, average 253mm, average

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ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the width of the gloves	Size S Size M Size L Size XL	80 ± 10mm 95 ± 10mm 110 ± 10mm 120 ± 10mm	Size S Size M Size L Size XL	86mm, average 96mm, average 107mm, average 118mm, average

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Non-Clinical Testing (Cont'd)					
Test Method	**Purpose**	**Acceptance Criteria**		**Result**	
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the thickness of the gloves	Measured in single wall at approximate center of palm area			
		Palm	0.05mm, min	Size S Size M Size L Size XL	0.06mm, average 0.06mm, average 0.06mm, average 0.06mm, average
		Measured in single wall at 13±3mm from the tip of middle finger			
		Finger	0.05mm, min	Size S Size M Size L Size XL	0.08mm, average 0.08mm, average 0.11mm, average 0.10mm, average
ASTM D6319-19 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		Size S Size M Size L Size XL	23 MPa, average 22 MPa, average 22 MPa, average 22 MPa, average
		After Ageing Tensile Strength 14Mpa, min for all sizes		Size S Size M Size L Size XL	23 MPa, average 23 MPa, average 23 MPa, average 22 MPa, average
	To determine the physical properties- Ultimate Elongation	**Before Ageing** Ultimate Elongation 500%, min for all sizes		Size S Size M Size L Size XL	524%, average 522%, average 523%, average 536%, average
		After Ageing Ultimate Elongation 400%, min for all sizes		Size S Size M Size L Size XL	538%, average 532%, average 530%, average 523%, average

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Biocompatibility Testing			
Test Method	**Purpose**	**Acceptance Criteria**	**Result**
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization **(Animal Irritation Test)**	To determine the potential of the material under test to produce dermal irritation in Rabbits	Under the condition of study not an irritant.	There was no observable irreversible alteration on the skin at the sites of contact with the test material. The Primary Irritation Index (PII) was "0". The test material was not corrosive, and the Primary Irritation Response Category is therefore "negligible", thereof met the requirement.
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization **(Dermal Sensitization Assay Test)**	To determine the skin sensitization potential of the material both in terms of induction and elicitation in Guinea pig	Under the condition of the study not a sensitizer.	There was no sensitization induced by the application of the test material on the albino guinea pigs under the condition of this test, thereof met the requirement.
ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity **(MEM Elution Assay)**	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface)	Under the conditions of study non cytotoxic	Under the conditions of the study, cytotoxic.
ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity **(Acute Systemic Toxicity)**	To provide information on health hazards likely to arise from a short-term exposure to the extracts of test material by intravenous and intraperitoneal injection in mice	Not induce systemic toxicity	Under the condition of this study, the single dose acute systemic toxicity of extracts from test material using both normal saline and sesame oil, shown non toxic effects, thereof met the requirement.

Non-clinical tests were carried out to demonstrate product performance conformity with standards referenced.

The following bench tests were performed:

<u>Non-clinical tests</u>
- Residual Powder Content
- Physical Properties
- Physical Dimension
- Freedom from Holes

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Biocompatibility Testing
- Animal Irritation Test
- Dermal Sensitization Assay
- Cytotoxicity Test (MEM Elution Assay)
- Acute Systemic Toxicity

The results from these performance evaluations demonstrated that the Nitrile Powder Free Blue Examination Gloves, Non-Sterile met the acceptance criteria defined in standards referenced

10.0 Summary of Clinical Testing: Clinical Testing is not needed for this device

11.0 Conclusion The conclusion drawn from the non-clinical test demonstrate that the subject device in 510(K) submission, Nitrile Powder Free Blue Examination Gloves, Non-Sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate device K210369.

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