June 6, 2025

Mah Sing Healthcare Sdn. Bhd.
Ivan Tan Chee Wei
Deputy General Manager, QA&RA
Lot 6478, Lorong Sungai Puloh/KU6,
Kawasan Industri Sungai Puloh,
Klang, Selangor 42100
Malaysia

Re: K243694
Trade/Device Name: Nitrile Powder Free Examination Glove with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate - Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: November 29, 2024
Received: November 29, 2024

Dear Ivan Tan Chee Wei:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D, Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243694

Device Name
Nitrile Powder Free Examination Glove with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate - Blue

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (2023), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Tested Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time in minutes
*Carmustine	3.3mg/ml	22.5
Cisplatin	1 mg/ml	>240
Cyclophospha	20 mg/ml	>240
Dacarbazine	10 mg/ml	>240
Doxorubicin, HCl	2 mg/ml	>240
Etoposide	20 mg/ml	>240
Fluorouracil	50 mg/ml	>240
Methotrexate	25 mg/ml	>240
Mitomycin	0.5 mg/ml	>240
Oxaliplatin	5 mg/ml	>240
Paclitaxel	6 mg/ml	>240
*Thiotepa	10 mg/ml	34.5
Vincristine	1 mg/ml	>240

Tested Opioid Drugs	Concentration	Minimum Breakthrough Detection Time in minutes
Fentanyl Citrate Injection	100mcg/2ml	>240

Warning: Do not use with Carmustine and Thiotepa.
*Note:
Please note that the following drugs have low permeation times:
(1) Carmustine – 22.5 minutes
(2) Thiotepa – 34.5 minutes.

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: **K243694**

510 (K) SUMMARY

1.0 Submitter name/ Contact details	Mah Sing Healthcare Sdn Bhd Lot 6478, Lorong Sungai Puloh/KU6, Kawasan Industri Sungai Puloh, Klang, Selangor 42100 **MALAYSIA** Name: Ivan Tan Chee Wei (Mr) Title: Deputy General Manager, QA&RA E-mail: ivan.tan@mshealthcare.com Tel: +60-3-3396 2288, Extn: 2213 Fax: +60-3-3396 2299
2.0 Summary Preparation Date	June 6, 2025
3.0 Device Name & Classification	Trade Name: Nitrile Powder Free Examination Glove with Tremella Fuciformis Extracts, Tested For Use with Chemotherapy Drugs and Fentanyl Citrate – Blue Common Name: Nitrile Powder Free Patient Examination Glove Classification Name: Polymer Patient Examination Glove Classification Panel: General Hospital Classification Regulation: 21 CFR 880.6250 Device Classification: I Product Code: LZA, LZC, OPJ, QDO
4.0 Identification of Predicate Device	Trade Name: Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 510(k) Number: K240080 Product Code: LZA, LZC, OPJ, QDO Manufacture's Name: Syntex Healthcare Products Co., Ltd.
5.0 Description of Device	The Nitrile Powder Free Examination Glove with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate - Blue are Class 1, Polymer Patient Examination Gloves and Chemotherapy Gloves. The glove is made of Nitrile Butadiene Rubber. They are ambidextrous with beaded cuffs, fingertip texture and come in different sizes - Small, Medium, Large and Extra Large. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and fentanyl citrate as per ASTM D6978-05(2023). The gloves are single use and provided non-sterile.

6.0 Indications for Use

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

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (2023), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Tested Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time in minutes
*Carmustine	3.3mg/ml	22.5
Cisplatin	1 mg/ml	>240
Cyclophosphamide	20 mg/ml	>240
Dacarbazine	10 mg/ml	>240
Doxorubicin, HCl	2 mg/ml	>240
Etoposide	20 mg/ml	>240
Fluorouracil	50 mg/ml	>240
Methotrexate	25 mg/ml	>240
Mitomycin	0.5 mg/ml	>240
Oxaliplatin	5 mg/ml	>240
Paclitaxel	6 mg/ml	>240
*Thiotepa	10 mg/ml	34.5
Vincristine	1 mg/ml	>240

Tested Opioid Drugs	Concentration	Minimum Breakthrough Detection Time in minutes
Fentanyl Citrate Injection	100mcg/2ml	>240

Warning: Do not use with Carmustine and Thiotepa.

***Note:**

Please note that the following drugs have low permeation times:

(1) Carmustine – 22.5 minutes

(2) Thiotepa – 34.5 minutes.

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7.0 Summary of the Technological Characteristic

Table 1

Characteristics and Parameters	Standard	Proposed Device (K243694)	Predicate device (K240080)	Comparison Analysis
Trade Name	-	Nitrile Powder Free Examination Gloves with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate – Blue	Aloe Vera Nitrile Examination Gloves (Green) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	*Different
Regulation Number	21 CFR Part 880.6250	21 CFR Part 880.6250	21 CFR Part 880.6250	Same
Product Code	-	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Classification	-	Class 1	Class 1	Same
Material	ASTM D 6319-19	Nitrile Butadiene Rubber	Synthetic Nitrile Rubber	Same
Indication for use		A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (2023), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves has been tested for use with Chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05 (2019).	Same
Design		1. Single use 2. Non-sterile 3. Powder free 4. Ambidextrous 5. Beaded cuff 6. Fingertip Textured	1. Single use 2. Non-sterile 3. Powder free 4. Ambidextrous 5. Beaded cuff	Similar
Color	-	Blue	Green	**Different
Coating	-	Tremella Fuciformis coated on the donning surface	Aloe coated on the donning surface	***Different

** The trade name will be provided on the labeling, so the difference does not affect the safety and effectiveness of the device.*
*** The subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not affect the safety and effectiveness of the device.*
**** The subject device contains **Tremella Fuciformis**, while the predicate device uses **Aloe**. Both ingredients are non-animal derived. Biocompatibility testing for both devices is identical, and the subject device has passed the performance testing, all of which met the required standards. Therefore, the difference in coating does not affect the safety and effectiveness of the device.*

Characteristics and Parameters	Standard	Subject Device	Predicate device (K240080)	Comparison Analysis
Chemotherapy Drug Permeation Test	ASTM D6978-05			
Tested Chemotherapy Drugs and Fentanyl citrate	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine	3.3mg/ml	**22.5**	**21.2**	Similar Below 240 minutes permeation times
Cisplatin	1 mg/ml	>240	>240	Same
Cyclophosphamide	20 mg/ml	>240	>240	Same
Dacarbazine	10 mg/ml	>240	>240	Same
Doxorubicin, HCl	2 mg/ml	>240	>240	Same
Etoposide	20 mg/ml	>240	>240	Same
Fluorouracil	50 mg/ml	>240	>240	Same
Methotrexate	25 mg/ml	>240	>240	Same
Mitomycin	0.5 mg/ml	>240	>240	Same
Oxaliplatin	5 mg/ml	>240	Not tested	*Different
Paclitaxel	6 mg/ml	>240	>240	Same
*Thiotepa	10 mg/ml	**34.5**	**24.9**	Similar Below 240 minutes permeation times
Vincristine	1 mg/ml	>240	>240	Same
Fentanyl Citrate Injection	100 mcg/2ml	>240	>240	Same

**The labeling of the subject device will include information on the minimum breakthrough time for chemotherapy drugs. This difference, along with the similarities to the predicate device, does not affect the safety or effectiveness of the device.*

Characteristics and Parameters	Standard	Subject Device	Predicate device (K240080)	Comparison Analysis
Length S: Min.220mm M: Min.230mm L: Min.230mm XL: Min.230mm	ASTM D 6319-19	S: 242 - 251mm M: 245 - 253mm L: 247 - 255mm XL: 249- 255mm	XS:≥ 220mm S: ≥ 220mm M: ≥ 230mm L: ≥ 230mm XL: ≥ 230mm XXL: ≥ 230mm	*Similar
Width S: 70mm – 90mm M: 85mm – 105mm L: 100mm – 120mm XL:110mm – 130mm	ASTM D 6319-19	S: 86 - 88mm M: 98 - 99mm L: 105 - 110mm XL: 117 - 119mm	XS: 70 ± 10mm S: 80 ± 10mm M: 95 ± 10mm L: 110 ± 10mm XL: 120 ± 10mm XXL: 130 ± 10mm	*Similar
Finger Thickness (Minimum 0.05mm)	ASTM D 6319-19	S: Minimum 0.08mm M: Minimum 0.08mm L: Minimum 0.08mm XL: Minimum 0.09mm	Minimum 0.05	Similar

Palm Thickness (Minimum 0.05mm)	ASTM D 6319-19	S: Minimum 0.06mm M: Minimum 0.06mm L: Minimum 0.06mm XL: Minimum 0.06mm	Minimum 0.05	Similar

Tensile Strength (Before aging) Minimum 14 MPa	ASTM D 6319-19	S: Minimum 33MPa M: Minimum 35MPa L: Minimum 36MPa XL: Minimum 34MPa	Minimum 14 MPa	Similar
Ultimate Elongation (before aging) Minimum 500%	ASTM D 6319-19	S: Minimum 551% M: Minimum 541% L: Minimum 531% XL: Minimum 523%	Minimum 500%	Similar
Tensile Strength (After accelerated aging) Minimum 14 MPa	ASTM D 6319-19	S: Minimum 34MPa M: Minimum 35MPa L: Minimum 34MPa XL: Minimum 34MPa	Minimum 14 MPa	Similar
Ultimate Elongation (after accelerated aging) Minimum 400%	ASTM D 6319-19	S: Minimum 532% M: Minimum 523% L: Minimum 505% XL: Minimum 504%	Minimum 400%	Similar
Freedom of Holes Meet AQL 2.5 at G1	ASTM D 5151-19	Meet AQL 2.5 with G1	Meet AQL 2.5 with G1	Same
Residual powder test (Less than 2mg/glove)	ASTM D 6124-06	S: 0.63mg/glove M: 1.02mg/glove L: 0.28mg/glove XL: 0.38mg/glove	≤ 2mg per glove	Similar
In vitro Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Under the condition of this test, exhibited cytotoxicity reactivity from 100.0% extract concentration to 25.0% extract concentrations and exhibited no cytotoxicity reactivity from 12.5% extract concentration to 3.125% extract concentrations.	Under the condition of this study, the test article showed potential toxicity to L929 cells.	Similar
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Under the conditions of the study, there is no adverse acute toxic reaction.	Under the conditions of this study, no evidence of acute systemic toxicity from the test article	Similar
Animal Irritation Test	ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation	Under the conditions of the study, not an irritant	The test result showed that the response of the test article was categorized as negligible under the test condition.	Similar
Dermal Sensitization	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization	Under the conditions of the study, no evidence of skin sensitization.	Under the conditions of this study, the test article showed no evidence of causing skin sensitization	Similar

Bioburden	ISO 11737-1:2018 Sterilization of health care products — Microbiological methods - Part 1: Determination of a population of microorganisms on products	≤ 200 CFU/device	Not performed	**Different
Material-mediated pyrogenicity	USP <151>	Under the conditions of the study, non-pyrogenic	Not performed	**Different

** The predicate device is available in sizes XS and XXL, while the subject device does not offer these sizes. However, the subject device has been tested according to ASTM D6319-19 for dimensional requirements and has met all applicable standards. Therefore, the difference in sizes does not affect the safety and effectiveness of the device.*

***Additional tests were performed to address safety concerns with fungal-derived material.*

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8.0 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length: S: ≥220mm M/L/XL: ≥230mm Width: S: 80±10 mm M: 95±10 mm L: 110±10 mm XL: 120±10 mm Thickness: Palm: ≥0.05 mm Finger: ≥0.05 mm	Length: S: ≥220mm M/L/XL: ≥230mm Width: S: 86-88/Pass M: 98-99/Pass L: 105-110/Pass XL: 117-119/Pass Thickness: Palm: S-XL:0.06/Pass Finger: S-L: 0.08/Pass XL: 0.09/Pass
ASTM D5151 ASTM D6319	Watertightness Test for Detection of Holes	Meet AQL 2.5 with G1	Meet AQL 2.5 with G1
ASTM D6124 ASTM D6319	Powder Content	Meet the requirement of ASTM D 6124-06 ≤2.0mg	S: 0.63mg/glove M: 1.02mg/glove L: 0.28mg/glove XL: 0.38mg/glove Pass
ASTM D412 ASTM D6319	Physical Properties	Tensile Strength: before aging ≥14 Mpa after aging ≥14 Mpa Ultimate Elongation: before aging ≥500 % after aging ≥400%	Tensile Strength: Before aging: Pass After aging: Pass Ultimate Elongation: Before aging: Pass After aging: Pass
ASTM D6978	Chemotherapy drug and Fentanyl Citrate claim	The subject device was tested for use with chemotherapy drugs and Fentanyl Citrate	The following chemotherapy drugs and Fentanyl Citrate concentration had NO breakthrough detected up to 240 minutes and can be used with the device. Cisplatin (1mg/ml), Cyclophosphamide (20.0 mg/ml), Dacarbazine (10.0 mg/ml), Doxorubicin HCl (2.0 mg/ml) Etoposide (20.0 mg/ml)

			Fluorouracil (50.0 mg/ml), Methotrexate (25mg/ml), Mitomycin (0.5mg/ml), Oxaliplatin (5mg/ml), Paclitaxel (6.0 mg/ml), Vincristine (1mg/ml), Fentanyl Citrate Injection 100mcg/2ml The following chemotherapy drugs have low permeation times: Carmustine (3.3 mg/ml): 22.5 minutes ThioTEPA (10.0 mg/ml): 34.5 minutes
ISO 10993-5	Cytotoxicity	Non-cytotoxic	Under conditions of the study, device extract is cytotoxic.
ISO 10993-23	Irritation	Non-irritating	Under the conditions of the study, device is not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing	Under the conditions of the study, device is not a sensitizer. / Pass
ISO 10993-11	Acute Systemic Toxicity	Non-acute systemic toxicity	Under the conditions of the study, device did not show acute systemic toxicity in vivo. /pass
ISO 11737-1:2018	Bioburden Determination	≤ 200 CFU/device	80-119 CFU/glove
USP <151>	Material-Mediated Pyrogenicity	Non-pyrogenic	Under the conditions of the study, non-pyrogenic

9.0 Summary of Clinical Testing

Clinical Testing is not needed for this device.

10.0 Conclusion

The conclusion drawn from the nonclinical test demonstrates that the subject device Nitrile Powder Free Examination Gloves with Tremella Fuciformis Extract, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate – Blue is as safe, as effective, and performs as well as or better than the legally marketed predicate device K240080.