February 2, 2023
Mah Sing Healthcare Sdn Bhd
Ivan Tan Chee Wei
Senior QA Manager
Wisma Mah Sing, Penthouse Suite 1, 163 Jalan Sungai Besi
Kuala Lumpur, Kuala Lumpur 57100
Malaysia

Re: K223415
Trade/Device Name: Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO

Dear Ivan Tan Chee Wei:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 01/27/23. Specifically, FDA is updating this SE Letter to correct the contact name to include the two middle names as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Bifeng Qian, OHT4: Office of Surgical and Infection Control Devices, at: 301-796-2261 or bifeng.qian@fda.hhs.gov.

Sincerely,

Bifeng Qian -S

Bifeng Qian, MD, 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

January 26, 2023

Mah Sing Healthcare Sdn Bhd
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Re: K223415
Trade/Device Name: Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: November 1, 2022
Received: November 10, 2022

Dear Ivan 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 (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,

Bifeng Qian -S

Bifeng Qian, M.D. Ph.D.
Assistant Director
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and Plastic Surgery Devices
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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)*
K223415

Device Name
Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate

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.
These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 (2019), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drugs are as follows:

Test Chemotherapy Drugs Concentration	Minimum Breakthrough Detection Time in minutes
*Carmustine 3.3mg/ml	14.1
Cisplatin1 mg/ml	>240
Cyclophosphamide 20 mg/ml	>240
Dacarbazine 10 mg/ml	>240
Doxorubicin, HCl2 mg/ml	>240
Etoposide20 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	57.2
Vincristine 1 mg/ml	>240

Test Fentanyl Citrate are as follows:

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

Warning: Do not use with Carmustine and Thiotepa.
Please note that the following drugs have low permeation times:
(1)Carmustine – 14.1 minutes
(2)Thiotepa – 57.2 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.

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

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Premarket Notification [510(k)] No: K223415

510 (K) SUMMARY

1.0 Device Name	Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate.
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: Ivan Tan Chee Wei (Mr) E-mail: ivan.tan@mshealthcare.com Tel: +60-3-3396 2288, Extn: 2213 Fax: +60-3-3396 2299
3.0 Summary Preparation Date	January 18, 2023
4.0 Device Name & Classification	Trade Name: Nitrile Powder Free Blue Patient Examination Gloves Non-sterile, Tested for use with Chemotherapy Drugs and Fentanyl Citrate. Common Name: Nitrile Powder Free Patient Examination Glove Classification Name: Patient Examination Gloves Specialty Polymer Patient Examination Gloves Device Classification: I Regulation Number: 21 CFR 880.6250 Panel: General Hospital Product Code: LZC, LZA, OPJ, QDO
5.0 Identification of The Legally Marketed Device	Predicate Device Name: Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use With Chemotherapy Drugs and Fentanyl Citrate Predicate 510(K) Number: K192954 Manufacture's Name: Comfort Rubber Gloves Industries Sdn Bhd.

6.0 Description of Device

Nitrile Powder Free Blue Patient Examination Gloves Non-sterile, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate meets all the requirements of ASTM standards D6319-19, D6978-05 (2019) and FDA 21 CFR 880.6250.

Nitrile Powder Free Blue Patient Examination Gloves Non-sterile, Tested For Use With Chemotherapy Drugs are Class I patient examination gloves bear the product code Nitrile – LZA, LZC, OPJ and QDO (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 i.e., can be worn on right hand or left hand, single use disposable devices that come in five sizes (XS, S, M, L and XL). The physical properties of glove, i.e., tensile strength meet ASTM D 6319-19.

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.
These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 (2019), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drugs are as follows:

Test Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time in minutes
*****Carmustine	3.3mg/ml	14.1
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	57.2
Vincristine	1 mg/ml	>240

Test Fentanyl Citrate are as follows:

Test Chemotherapy 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 – 14.1 minutes
(2) Thiotepa – 57.2 minutes.

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8.0 Summary of the Technological Characteristic of the Device

Nitrile Powder Free Blue Patient Examination Gloves Non-sterile, Tested For Use with Chemotherapy Drugs and Fentanyl Citrate meets all the requirements of ASTM standards D6319-19, D6978-05 (2019) and FDA 21 CFR 880.6250.

Table 1

Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
510(k) Number	-	K223415	K192954	Different
Manufacturer	-	Mah Sing Healthcare Sdn. Bhd.	Comfort Rubber Gloves Industries Sdn Bhd	Different
Name of device		Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested for use with chemotherapy drugs and fentanyl citrate	Blue Colored, Powder Free Nitrile Examination Gloves, Non-Sterile, and Tested for use with chemotherapy drugs and fentanyl citrate	Similar
Device Classification Name/Regulation Number	Patient Examination Glove, 21 CFR Part 880.6250	Patient Examination Glove, 21 CFR Part 880.6250	Patient Examination Glove, 21 CFR Part 880.6250	Same
Product Code	-	LZA, LZC, OPJ, QDO	LZA, LZC, QDO	Same
Classification	-	Class 1	Class 1	Same
Raw Rubber Material	ASTM D 6319-19	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same

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Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
Chemotherapy Drug Permeation Test	ASTM D6897-05			
Test Chemotherapy Drugs	**Concentration**	**Minimum Breakthrough Detection Time (min)**		
*Carmustine	3.3mg/ml	**14.1**	**18.2**	Similar Below 240 minutes permeation times
Cisplatin	1 mg/ml	>240	>240	Similar
Cyclophosphamide	20 mg/ml	>240	>240	Similar
Dacarbazine	10 mg/ml	>240	>240	Similar
Doxorubicin, HCl	2 mg/ml	>240	>240	Similar
Etoposide	20 mg/ml	>240	>240	Similar
Fluorouracil	50 mg/ml	>240	>240	Similar
Methotrexate	25 mg/ml	>240	Not tested	Optional, Subject device perform additional Chemotherapy drug test
Mitomycin	0.5 mg/ml	>240	Not tested	Optional, Subject device perform additional Chemotherapy drug test
Oxaliplatin	5 mg/ml	>240	Not tested	Optional, Subject device perform additional Chemotherapy drug test
Paclitaxel	6 mg/ml	>240	>240	Similar
*Thiotepa	10 mg/ml	**57.2**	**57.3**	Similar Below 240 minutes permeation times
Vincristine	1 mg/ml	>240	>240	Similar
Fentanyl Citrate Injection	100 mcg/2ml	>240	>240	Similar

Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
Length XS: Min. 220mm S: Min.220mm M: Min.230mm L: Min.230mm XL: Min.230mm	ASTM D 6319-19	XS: 245 -251mm S: 247 - 255mm M: 245 - 255mm L: 247 - 255mm XL: 247- 252mm	Min. 240 mm	Similar
Width XS:60mm - 80mm S: 70mm – 90mm M: 85mm – 105mm L: 100mm – 120mm XL:110mm – 130mm	ASTM D 6319-19	XS: 76 - 78mm S: 82 - 88mm M: 95 - 99mm L: 111 - 118mm XL: 120 - 127mm	Not stated by predicate device	Similar, subject device meet requirements of ASTM D6319
Palm Thickness (Minimum 0.05mm)	ASTM D 6319-19	Average: 0.06mm	Min 0.05	Similar
Finger Thickness (Minimum 0.05mm)	ASTM D 6319-19	Average: 0.07mm	Min 0.05	Similar
Tensile Strength (Before aging) Minimum 14 MPa	ASTM D 6319-19	Average: 25.29MPa	Meets	Similar
Tensile Strength (After accelerated aging) Minimum 14 MPa	ASTM D 6319-19	Average: 27.11MPa	Meets	Similar
Ultimate Elongation (before aging) Minimum 500%	ASTM D 6319-19	Average: 551%	Meets	Similar
Ultimate Elongation (after accelerated aging) Minimum 400%	ASTM D 6319-19	Average: 449%	Meets	Similar
Freedom of Holes Meet AQL 2.5 at G1	ASTM D 5151-19	Meet AQL 1.5 with G1	Passes	Similar
Residual powder test (Less than 2mg/glove)	ASTM D 6124-06	Average powder residue for each size. XS: 0.25mg/glove S: 0.20mg/glove M: 0.28mg/glove L: 0.28mg/glove XL: 0.38mg/glove	Meets	Similar
Animal Irritation Test	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Passed. Under the conditions of study, not an irritant	Passes Under the conditions of the study, the subject device is non-irritating	Similar
Dermal Sensitization	ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Passed. Under the conditions of study, not a sensitizer	Passes Under the conditions of the study, the subject device is non-sensitization	Similar
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Not induce acute systemic toxicity	Passes Under the conditions of the study, the subject showed no adverse biological reaction	Similar

Characteristics and Parameters	Standard	Proposed Device	Predicate device	Comparison Analysis
Indication for use	-	Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is 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. These gloves were 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 Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Same intended use

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 XS Size S Size M Size L Size XL	0.25mg /glove 0.20mg /glove 0.28mg /glove 0.28mg /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 XS Size S Size M Size L Size XL	220mm, min 220mm, min 230mm, min 230mm, min 230mm, min	Size XS Size S Size M Size L Size XL	245 - 251mm 247 - 255mm 245 - 255mm 247 - 255mm 247- 252mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the width of the gloves	Size XS Size S Size M Size L Size XL	70 ± 10mm 80 ± 10mm 95 ± 10mm 110 ± 10mm 120 ± 10mm	Size XS Size S Size M Size L Size XL	76 - 78mm 82 - 88mm 95 - 99mm 111 - 118mm 120 - 127mm

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 XS Size S Size M Size L Size XL	0.06 - 0.06mm 0.06 - 0.07mm 0.06 - 0.07mm 0.06 - 0.06mm 0.06 - 0.06mm
		Measured in single wall at 13±3mm from the tip of middle finger			
		Finger	0.05mm, min	Size XS Size S Size M Size L Size XL	0.07 – 0.07mm 0.07 - 0.08mm 0.07 - 0.08mm 0.07 - 0.08mm 0.07 - 0.08mm
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 XS Size S Size M Size L Size XL	23.97 MPa, average 26.35 MPa, average 25.15 MPa, average 25.11 MPa, average 25.85 MPa, average
		After Ageing Tensile Strength 14Mpa, min for all sizes		Size XS Size S Size M Size L Size XL	27.11 MPa, average 26.78 MPa, average 29.22 MPa, average 25.94 MPa, average 26.50 MPa, average
	To determine the physical properties- Ultimate Elongation	**Before Ageing** Ultimate Elongation 500%, min for all sizes		Size XS Size S Size M Size L Size XL	571%, average 571%, average 538%, average 552%, average 525%, average
		After Ageing Ultimate Elongation 400%, min for all sizes		Size XS Size S Size M Size L Size XL	462%, average 458%, average 434%, average 457%, average 434%, average

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Non-Clinical Testing (Cont'd)			
Test Method	**Purpose**	**Acceptance Criteria**	**Result**
ASTM D6897-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	To provide a uniform procedure for assessing the resistance of medical glove materials to permeation by chemotherapy drugs, and to establish a consistent reporting of the test data.	>240 minutes	*Carmustine 3.3mg/ml = 4.1 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 = 57.2 Vincristine 1 mg/ml = >240 Fentanyl Citrate Injection 100mcg/2ml = >240

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 10993-11 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:

Non-clinical tests
- Residual Powder Content
- Physical Properties
- Physical Dimension
- Freedom from Holes
- Chemotherapy Drug Permeation Test

Biocompatibility Testing
- Animal Irritation Test
- Dermal Sensitization Assay
- Acute Systemic Toxicity

The results from these performance evaluations demonstrated that the Nitrile Powder Free Blue Patient Examination Gloves, Non-Sterile, Tested for Use With Chemotherapy Drugs and Fentanyl Citrate 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 is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192954.

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