June 17, 2025

KL-Kepong Rubber Products SDN. BHD.
Phooi Yann Cheng
Senior Technical Manager
Lot 134905, ¾ Mile Off Jalan Bercham
Kawasan Perindustrian Bercham
Ipoh, Perak 31400
Malaysia

Re: K243133
Trade/Device Name: Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid
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: June 16, 2025
Received: June 16, 2025

Dear Phooi Yann Cheng:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243133

Device Name
Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

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, fentanyl citrate and gastric acid as per ASTM D6978-05 (2023) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs:

The following drugs and concentration had NO breakthrough detected up to 240 minutes:

Bendamustine HCl (5 mg/mL)
Bleomycin Sulfate (15 mg/mL)
Busulfan (6 mg/mL)
Carboplatin (10 mg/mL)
Carfilzomib (2 mg/mL)
Cetuximab (Erbitux) (2 mg/mL)
Chloroquine (50 mg/mL)
Cisplatin (1 mg/mL)
Cladribine (1 mg/mL)
Cyclophosphamide (20 mg/mL)
Cyclosporin A (100 mg/mL)
Cytarabine HCl (100 mg/mL)
Cytovene (10 mg/mL)
Dacarbazine (10 mg/mL)
Daunorubicin HCl (5 mg/mL)
Decitabine (5 mg/mL)
Docetaxel (10 mg/mL)
Doxorubicin HCl (2 mg/mL)
Epirubicin HCl (2 mg/mL)
Etoposide (20 mg/mL)
Fludarabine Phosphate (25 mg/mL)
Fluorouracil (50 mg/mL)
Fulvestrant (50 mg/mL)
Gemcitabine HCl (38 mg/mL)
Idarubicin HCl (1 mg/mL)
Ifosfamide (50 mg/mL)
Irinotecan HCl (20 mg/mL)
Mechlorethamine HCl (1 mg/mL)
Melphalan HCl (5 mg/mL)
MESNA (100 mg/mL)
Methotrexate (25 mg/mL)
Mitomycin C (0.5 mg/mL)
Mitoxantrone HCl (2 mg/mL)
Oxaliplatin (2 mg/mL)
Paclitaxel (6 mg/mL)
Pemetrexed (25 mg/mL)

Propofol (10 mg/mL)
Raltitrexed (0.5 mg/mL)
Retrovir (10 mg/mL)
Rituximab (10 mg/mL)
Temsirolimus (25 mg/mL)
Topotecan HCl (1 mg/mL)
Triclosan (1 mg/mL)
Trisenox (Arsenic Trioxide) (1 mg/mL)
Velcade (Bortezomib) (1 mg/mL)
Vidaza (Azacitidine) (25 mg/mL)
Vinblastine Sulfate (1 mg/mL)
Vincristine Sulfate (1 mg/mL)
Vinorelbine Tartrate (10 mg/mL)
Zoledronic Acid (0.8 mg/mL)

The following chemotherapy drugs and concentration showed breakthrough detected in less than 60 minutes:

Carmustine (3.3 mg/mL), breakthrough detected at 55.5 minutes
Thiotepa (10 mg/mL), breakthrough detected at 50.8 minutes

Warning: Not recommended for use with Carmustine and Thiotepa

The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes:

Fentanyl Citrate Injection (100mcg/2mL)
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

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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510(k) SUMMARY

K243133

Date Summary Prepared: 17 June 2025

1. Submitter's Identification:

KL-KEPONG RUBBER PRODUCTS SDN. BHD.
Lot 134905, ¾ Mile Off Jalan Bercham,
Kawasan Perindustrian Bercham,
31400 Ipoh, Perak, Malaysia.

Contact: Cheng Phooi Yann
Tel: +605-541 7337
Email: py.cheng@klkrp.com.my

2. Name of the Device:

Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid

3. Regulatory Information:

Product Code, Regulation Name:	LZA, Polymer Patient Examination Glove LZC, Medical Glove, Specialty OPJ, Medical Gloves with Chemotherapy Labeling Claims - Test for Use With Chemotherapy Drugs QDO, Fentanyl And Other Opioid Protection Glove
Regulatory Class:	Class I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital

4. Predicate Device Information:

Predicate Device:	K231938
Trade/Device Name:	Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid
Device Classification Name:	Polymer Patient Examination Glove
Device Class:	Class I
Product Code:	LZA, LZC, OPJ, QDO
Applicant Name:	O&M Halyard, Inc.

5. Device Description:

The subject device, Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid is a single use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. This product demonstrated reduced potential for sensitizing users to chemical additives, supported by a negative skin sensitization test (Modified Draize-95 Test) and tested for use with chemotherapy drugs, fentanyl citrate and gastric acid.

The gloves are made of nitrile rubber, powder free, ambidextrous with beaded cuff. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that facilitates the user in donning the gloves without using lubricant and donning powder on the glove surface. These gloves are offered in six sizes (XS, S, M, L, XL, XXL), and supplied in non-sterile state.

6. 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, fentanyl citrate and gastric acid as per ASTM D6978-05 (2023) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs:

The following drugs and concentration had NO breakthrough detected up to 240 minutes:
Bendamustine HCl (5 mg/mL)
Bleomycin Sulfate (15 mg/mL)
Busulfan (6 mg/mL)
Carboplatin (10 mg/mL)
Carfilzomib (2 mg/mL)
Cetuximab (Erbitux) (2 mg/mL)
Chloroquine (50 mg/mL)
Cisplatin (1 mg/mL)
Cladribine (1 mg/mL)
Cyclophosphamide (20 mg/mL)
Cyclosporin A (100 mg/mL)
Cytarabine HCl (100 mg/mL)
Cytovene (10 mg/mL)
Dacarbazine (10 mg/mL)
Daunorubicin HCl (5 mg/mL)
Decitabine (5 mg/mL)
Docetaxel (10 mg/mL)
Doxorubicin HCl (2 mg/mL)

Epirubicin HCl (2 mg/mL) Etoposide (20 mg/mL) Fludarabine Phosphate (25 mg/mL) Fluorouracil (50 mg/mL) Fulvestrant (50 mg/mL) Gemcitabine HCl (38 mg/mL) Idarubicin HCl (1 mg/mL) lfosfamide (50 mg/mL) Irinotecan HCl (20 mg/mL) Mechlorethamine HCl (1 mg/mL) Melphalan HCl (5 mg/mL) MESNA (100 mg/mL) Methotrexate (25 mg/mL) Mitomycin C (0.5 mg/mL) Mitoxantrone HCl (2 mg/mL) Oxaliplatin (2 mg/mL) Paclitaxel (6 mg/mL) Pemetrexed (25 mg/mL) Propofol (10 mg/mL) Raltitrexed (0.5 mg/mL) Retrovir (10 mg/mL) Rituximab (10 mg/mL) Temsirolimus (25 mg/mL) Topotecan HCl (1 mg/mL) Triclosan (1 mg/mL) Trisenox (Arsenic Trioxide) (1 mg/mL) Velcade (Bortezomib) (1 mg/mL) Vidaza (Azacitidine) (25 mg/mL) Vinblastine Sulfate (1 mg/mL) Vincristine Sulfate (1 mg/mL) Vinorelbine Tartrate (10 mg/mL) Zoledronic Acid (0.8 mg/mL)
The following chemotherapy drugs and concentration showed breakthrough detected in less than 60 minutes: Carmustine (3.3 mg/mL), breakthrough detected at 55.5 minutes Thiotepa (10 mg/mL), breakthrough detected at 50.8 minutes Warning: Not recommended for use with Carmustine and Thiotepa
The following hazardous drugs (opioids) and concentration had NO breakthrough detected up to 240 minutes: Fentanyl Citrate Injection (100mcg/2mL) Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution

7. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table 1: Comparison to Predicate Device

COMPARISON CRITERIA	Subject Device	Predicate Device (K231938)	COMPARISON RESULTS
Manufacturer	KL-Kepong Rubber Products Sdn. Bhd.	O&M Halyard, Inc.	N/A
Device Name	Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid	Halyard STERLING* Nitrile Powder-Free Exam Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid	Similar
Device Classification Name/ Regulation Number	Polymer Patient Examination Glove/ 21 CFR Part 880.6250	Polymer Patient Examination Glove/ 21 CFR Part 880.6250	Similar
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC, OPJ, QDO	Similar
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, fentanyl citrate and gastric acid as per ASTM D6978-05 (2023) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	The device with Low Dermatitis Potential, Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid 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, fentanyl citrate and gastric acid as listed on the label.	Similar
Material	Nitrile	Nitrile	Similar
Powdered or powder free	Powder free	Powder free	Same
Single use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same

Color	Blue-Green	Grey	Different
Dimensions	Meet requirements of ASTM D6319 (XS, S, M, L, XL, XXL)	Meet requirements of ASTM D6319 (XS, S, M, L, XL)	Similar (Additional size XXL for subject device)
Physical properties	Meet requirements of ASTM D6319	Meet requirements of ASTM D6319	Similar
Freedom from Holes	Meet requirements of ASTM D5151	Meet requirements of ASTM D5151	Similar
Residual Powder	Meet requirements of ASTM D6124	Meet requirements of ASTM D6124	Similar
Chemotherapy Drugs Permeation Test as per ASTM D6978-05, minimum breakthrough detection time in minutes	54 drugs were tested Azacitidine (Vidaza) (25 mg/mL): Not tested Bendamustine HCl (5 mg/mL): > 240 Bleomycin Sulfate (15 mg/mL): > 240 Bortezomib (Velcade) (1 mg/mL): Not tested Busulfan (6 mg/mL): > 240 Capecitabine (26 mg/mL): Not Tested Carboplatin (10 mg/mL): > 240 Carfilzomib (2 mg/mL): > 240 Carmustine (3.3 mg/ml): 55.5 Cetuximab (Erbitux) (2 mg/mL): > 240 Chloroquine	52 drugs were tested Azacitidine (Vidaza) (25 mg/mL): > 240 Bendamustine HCl (5 mg/mL): > 240 Bleomycin Sulfate (Blenoxane) (15 mg/mL): > 240 Bortezomib (Velcade) (1 mg/mL): > 240 Busulfan (6 mg/mL): > 240 Capecitabine (26 mg/mL): > 240 Carboplatin (10 mg/mL): > 240 Carfilzomib (2 mg/mL): > 240 Carmustine (3.3 mg/ml): 22.9 Cetuximab (Erbitux) (2 mg/mL): > 240 Chloroquine	Minimum 9 drugs were tested. Similar Not to be claimed Same Same Not to be claimed Same Not to be claimed Same Same <240, same Same Additional test for

	(50 mg/mL): > 240	(50 mg/mL): Not Tested	subject device
	Cisplatin (1 mg/mL): > 240	Cisplatin (1 mg/mL): > 240	Same
	Cladribine (1 mg/mL): > 240	Cladribine (1 mg/mL): > 240	Same
	Cyclophosphamide (20 mg/mL): > 240	Cyclophosphamide (20 mg/mL): > 240	Same
	Cyclosporin A (100 mg/mL): > 240	Cyclosporin A (100 mg/mL): Not Tested	Additional test for subject device
	Cytarabine HCl (100 mg/mL): > 240	Cytarabine HCl (Cytosine) (100 mg/mL): > 240	Same
	Cytovene (10 mg/mL): > 240	Cytovene (10 mg/mL): Not Tested	Additional test for subject device
	Dacarbazine (10 mg/mL): > 240	Dacarbazine (DTIC) (10 mg/mL): > 240	Same
	Dactinomycin (0.5 mg/mL): Not Tested	Dactinomycin (0.5 mg/mL): > 240	Not to be claimed
	Daunorubicin HCl (5 mg/mL): > 240	Daunorubicin HCl (5 mg/mL): > 240	Same
	Decitabine (5 mg/mL): > 240	Decitabine (5 mg/mL): > 240	Same
	Docetaxel (10 mg/mL): > 240	Docetaxel (10 mg/mL): Not Tested	Additional test for subject device
	Docetaxel HCl (20 mg/mL): Not Tested	Docetaxel HCl (20 mg/mL): > 240	Not to be claimed
	Doxorubicin HCl (2 mg/mL): > 240	Doxorubicin HCl (2mg/mL): > 240	Same
	Epirubicin HCl (2 mg/mL): > 240	Epirubicin HCl (Ellence) (2mg/mL): > 240	Same
	Etoposide (20 mg/mL): > 240	Etoposide (20mg/mL): > 240	Same
	Floxuridine	Floxuridine	Not to be claimed

	(100mg/mL): Not Tested	(100mg/mL): > 240	
	Fludarabine Phosphate (25 mg/mL): > 240	Fludarabine Phosphate (25 mg/mL): Not Tested	Additional test for subject device
	Fluorouracil (50 mg/mL): > 240	5-Fluorouracil (50 mg/mL): > 240	Same
	Fulvestrant (50 mg/mL): > 240	Fulvestrant (50 mg/mL): Not Tested	Additional test for subject device
	Gemcitabine HCl (38 mg/mL): > 240	Gemcitabine HCl (38 mg/mL): > 240	Same
	Idarubicin HCl (1 mg/mL): > 240	Idarubicin HCl (1 mg/mL): > 240	Same
	lfosfamide (50 mg/mL): > 240	lfosfamide (IFEX) (50 mg/mL): > 240	Same
	Irinotecan HCl (20 mg/mL): > 240	Irinotecan HCl (20 mg/mL): > 240	Same
	Lenvatinib (20mg/mL): Not Tested	Lenvatinib (20mg/mL): > 240	Not to be claimed
	Leuprolide Acetate Salt (5 mg/mL): Not Tested	Leuprolide Acetate Salt (5 mg/mL): > 240	Not to be claimed
	Mechlorethamine HCl (1 mg/mL): > 240	Mechlorethamine HCl (1 mg/mL): > 240	Same
	Melphalan HCl (5 mg/mL): > 240	Melphalan HCl (5 mg/mL): > 240	Same
	MESNA (100 mg/mL): > 240	MESNA (100 mg/mL): Not Tested	Additional test for subject device
	Methotrexate (25 mg/mL): > 240	Methotrexate (25 mg/mL): > 240	Same
	Mitomycin C (0.5 mg/mL): > 240	Mitomycin C (0.5 mg/mL): > 240	Same
	Mitoxantrone HCl (2 mg/mL): > 240	Mitoxantrone HCl (2 mg/mL): > 240	Same
	Nelarabine	Nelarabine	Not to be claimed

	(5 mg/mL): Not Tested	(5 mg/mL): > 240	
	Oxaliplatin (2 mg/mL): > 240	Oxaliplatin (5 mg/mL): > 240	Same
	Paclitaxel (6 mg/mL): > 240	Paclitaxel (Taxol) (6 mg/mL): > 240	Same
	Pemetrexed (25 mg/mL): > 240	Pemetrexed (25 mg/mL): > 240	Same
	Propofol (10 mg/mL): > 240	Propofol (10 mg/mL): Not Tested	Additional test for subject device
	Raltitrexed (0.5 mg/mL): > 240	Raltitrexed (0.5 mg/mL): > 240	Same
	Retrovir (10 mg/mL): > 240	Retrovir (10 mg/mL): Not Tested	Additional test for subject device
	Rituximab (10 mg/mL): > 240	Rituximab (10 mg/mL): Not Tested	Additional test for subject device
	Sorafenib Tosylate (200 mg/mL): Not Tested	Sorafenib Tosylate (200 mg/mL): > 240	Not to be claimed
	Streptozocin (l00mg/mL): Not Tested	Streptozocin (l00mg/mL): > 240	Not to be claimed
	Tamoxifen (2 mg/mL): Not Tested	Tamoxifen (2 mg/mL): > 240	Not to be claimed
	Teniposide (10 mg/mL): Not Tested	Teniposide (10 mg/mL): > 240	Not to be claimed
	Temsirolimus (25 mg/mL): > 240	Temsirolimus (25 mg/mL): Not Tested	Additional test for subject device
	Thiotepa (10 mg/mL): 50.8	Thiotepa (10 mg/mL): 37.1	<240, same
	Topotecan HCl (1 mg/mL): > 240	Topotecan HCl (1 mg/mL): > 240	Same
	Triclosan (1 mg/mL): > 240	Triclosan (1 mg/mL): Not Tested	Additional test for subject device
	Trisenox (Arsenic Trioxide)	Trisenox (Arsenic	Same

	(1 mg/mL): > 240 Velcade (Bortezomib) (1 mg/mL): > 240 Vidaza (Azacitidine) (25 mg/mL): > 240 Vinblastine Sulfate (1 mg/mL): > 240 Vincristine Sulfate (1 mg/mL): > 240 Vinorelbine Tartrate (10 mg/mL): > 240 Zoledronic Acid (0.8 mg/mL): > 240 Fentanyl Citrate Injection (100 mcg/2 mL): > 240 Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution: > 240	Trioxide) (1 mg/mL): > 240 Velcade (Bortezomib) (1 mg/mL): Not Tested Vidaza (Azacitidine) (25 mg/mL): Not Tested Vinblastine Sulfate (1 mg/mL): > 240 Vincristine Sulfate (Oncovin) (1 mg/mL): > 240 Vinorelbine (10 mg/mL): > 240 Zoledronic Acid (0.8 mg/mL): Not Tested Fentanyl Citrate Injection (100 mcg/2 mL): > 240 Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution: > 240	 Additional test for subject device Additional test for subject device Same Same Same Additional test for subject device Same Same
Biocompatibility ISO 10993-10:2021 Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization	Under the conditions of the study, not a skin sensitizer.	Under the conditions of the study, the test article was considered non-sensitizing.	Same
Biocompatibility ISO 10993-11:2017 Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity	Under the conditions of the study, the test article did not elicit acute systemic toxicity.	Under the conditions of the study, the test article did not elicit acute systemic toxicity.	Same
Biocompatibility ISO 10993-23:2021 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation	Under the conditions of the study, not an irritant.	Under the conditions of the study, the test article was considered non-irritating.	Same

Clinical Test (Modified Draize-95 Test)	Under the conditions of the study, device was nonirritating and showed no clinical evidence of residual chemical additives that may induce Type IV allergy in human subject.	Under the conditions of the study, device was nonirritating and showed no clinical evidence of residual chemical additives that may induce Type IV allergy in human subject.	Same

8. Summary of Non-Clinical Tests Performed:

The non-clinical performance testing completed for the KL-Kepong Rubber Products Sdn. Bhd., Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid demonstrated that the subject device met the acceptance criteria or specification for the applicable test methodology or standard as shown below.

Table 2: Summary Non-Clinical Tests

Standard	Testing	Requirements	Result
ASTM D5151-19	Watertight Test (Freedom from Holes)	Pass Inspection Level G1, AQL 2.5	Pass
ASTM D6319-19	Physical Properties	Before Aging: Tensile strength: min 14MPa Ultimate elongation: min 500% After Aging: Tensile strength: min 14MPa Ultimate elongation: min 400%	Pass
ASTM D6319-19	Dimensions	Length XS: min 220mm S: min 220mm M: min 230mm L: min 230mm XL: min 230mm XXL: min 230mm Palm Width XS: 70 ± 10mm S: 80 ± 10mm M: 95 ± 10mm L: 110 ± 10mm XL: 120 ± 10mm XXL: 130 ± 10mm Thickness Finger: min 0.05mm	Pass

		Palm: min 0.05mm	
ASTM D6124-06	Residual Powder Content	Residual powder <2.0mg/glove	Pass
ASTM D6978-05	Chemotherapy Drugs Permeation Test	An assessment is made based on the permeation (breakthrough) of chemotherapy drugs through the glove material over a certain period of time	See above for details

Table 3: Summary of Biocompatibility Tests

Standard	Testing	Requirements	Result
ISO 10993-10:2021	Biological Evaluation of Medical Devices- Part 10: Test for Skin Sensitization	Under the conditions of testing, not a sensitizer	Pass
ISO 10993-11: 2017	Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity	Under the conditions of testing, no acute systemic toxicity	Pass
ISO 10993-23:2021	Biological Evaluation of Medical Devices- Part 23: Test for Irritation	Under the conditions of testing, not an irritant	Pass

9. Summary of Clinical Tests Performed:

The skin sensitization test ('Modified Draize-95' Test) of this medical device, Nitrile Examination Gloves with Low Dermatitis Potential, tested on 209 non-sensitized human subjects with inner surface and tested on 200 non-sensitized human subjects with outer surface are negative, hence meeting the requirements for the claim: This product demonstrated reduced potential for sensitizing users to rubber chemical additives as described in Guidance for Industry and FDA Staff - Medical Glove Guidance Manual.

10. Conclusion:

The conclusion drawn from the non-clinical tests and clinical tests demonstrates that the subject device, Nitrile Powder Free Examination Gloves with Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Gastric Acid are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K231938.