January 11, 2023

Iconic medicare sdn bhd
% A.C. Thirumaran
Official Correspondent
Integrated Assessment Services Pvt Ltd
1495, Manasarovar, 16th Main road, Anna Nagar West
Chennai, Tamil Nadu 600040
India

Re: K222181
Trade/Device Name: Iconic Blue Nitrile Glove - Tested for use with Chemotherapy Drugs & Fentanyl Citrate
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: December 22, 2022
Received: December 28, 2022

Dear A.C. Thirumaran:

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
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)*
K222181

Device Name
Iconic Blue Nitrile Glove- Tested for use with Chemotherapy Drugs & 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 and Fentanyl Citrate as per ASTM D6978-05 (2019).

The following chemicals have been tested with these gloves.

S.No	Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time (Specimen 1,2,3) (Minutes)
1	Carboplatin,	10 mg/ml (10,000 ppm)	>240 min.
2	Carmustine,	3.3 mg/ml (3,300 ppm)	26.6 (27.5,26.6,26.8)
3	Cisplatin,	1 mg/ml (1,000 ppm)	>240 min.
4	Cyclophosphamide,	20 mg/ml (20,000 ppm)	>240 min.
5	Dacarbazine,	10 mg/ml (10,000 ppm)	>240 min.
6	Doxorubicin HCl,	2 mg/ml (2,000 ppm)	>240 min.
7	Etoposide,	20 mg/ml (20,000 ppm)	>240 min.
8	Fluorouracil,	50 mg/ml (50,000 ppm)	>240 min.
9	Methotrexate,	25 mg/ml (25,000 ppm)	>240 min.
10	Mitomycin C,	0.5 mg/ml (500 ppm)	>240 min.
11	Mitoxantrone,	2 mg/ml (2,000 ppm)	>240 min.
12	Oxaliplatin,	5 mg/ml (5,000 ppm)	>240 min.
13	Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
14	Thiotepa,	10 mg/ml (10,000 ppm)	56.0 (58.4,56.5,56.0)
15	Vincristine Sulfate,	1 mg/ml (1,000 ppm)	>240 min.

S.No	Opiod Drugs	Concentration	Minimum Breakthrough Detection Time (Specimen 1,2,3) (Minutes)
16	Fentanyl Citrate Injection	100mcg/2mL	>240 min.

Please note that the following drugs have low permeation times:
Carmustine: 26.6 minutes
Thiotepa: 56.0 minutes
Warning - Please do not use with Carmustine and 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.

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510(K) Summary - K222181

ICONIC BLUE NITRILE GLOVE

Tested for use with Chemotherapy Drugs & Fentanyl Citrate

Preparation Date: January 11, 2023

1. **Submitter:**

Mr. Tan Cho Chia Managing Director
Company Name: Iconic Medicare Sdn Bhd.
Company Address: PMT 798, Lingkaran Cassia Selatan, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang.
Email: cctan@iconic.com.my

2. **Name of the Device**

Trade Name / Proprietary Name: Iconic Blue Nitrile Glove – Tested for use with Chemotherapy Drugs & Fentanyl Citrate.
Device Common Name: Non-Powdered Patient Examination Glove.
Device Classification Name: Polymer Patient Examination gloves (21 CFR 880.6250).
Device Class: Class I.
Product Code: LZA, LZC, QDO, OPJ
510k Number: K222181

3. **Official Correspondent**

Mr.A.C.Thirumaran
Integrated Assessment Services Private Limited
No.1495, Manasarovar, 16th Main Road, Anna Nagar west, Chennai- 600040, India.
Email: iasfda16@gmail.com

4. **Identification of the Legally Marketed Predicate Device:**

Predicate Device: Better Care Plastic Technology Co., Ltd.
510k Number: - K221269
Device Name: Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Device Classification Name: Polymer Patient Examination gloves (21 CFR 880.6250).
Device Class: Class I.
Product Code: LZA, LZC, QDO

5. Device Description

The subject device in this 510(k) Notification is Iconic Blue Nitrile Glove – Tested for use with Chemotherapy Drugs & Fentanyl Citrate, Powder Free & Non sterile Nitrile Examination Glove. The subject device is a patient examination glove made from Nitrile compound (Per 21 CFR 880.6250, class I). The device meets the specifications in ASTM D6319-19 Standard specification for Nitrile Examination Gloves & ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. The available sizes of the subject devices are Small, Medium, Large, X-Large.

6. Intended use of the Device

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 and Fentanyl Citrate as per ASTM D6978-05 (2019).

The following chemicals have been tested with these gloves.

S.No	Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time (Specimen 1,2,3) (Minutes)
1	Carboplatin,	10 mg/ml (10,000 ppm)	>240 min.
2	Carmustine,	3.3 mg/ml (3,300 ppm)	26.6 (27.5,26.6,26.8)
3	Cisplatin,	1 mg/ml (1,000 ppm)	>240 min.
4	Cyclophosphamide,	20 mg/ml (20,000 ppm)	>240 min.
5	Dacarbazine,	10 mg/ml (10,000 ppm)	>240 min.
6	Doxorubicin HCI,	2 mg/ml (2,000 ppm)	>240 min.
7	Etoposide,	20 mg/ml (20,000 ppm)	>240 min.
8	Fluorouracil,	50 mg/ml (50,000 ppm)	>240 min.
9	Methotrexate,	25 mg/ml (25,000 ppm)	>240 min.
10	Mitomycin C,	0.5 mg/ml (500 ppm)	>240 min.
11	Mitoxantrone,	2 mg/ml (2,000 ppm)	>240 min.
12	Oxaliplatin,	5 mg/ml (5,000 ppm)	>240 min.
13	Paclitaxel,	6 mg/ml (6,000 ppm)	>240 min.
14	Thiotepa,	10 mg/ml (10,000 ppm)	56.0 (58.4,56.5,56.0)
15	Vincristine Sulfate,	1 mg/ml (1,000 ppm)	>240 min.

S.No	Opiod Drugs	Concentration	Minimum Breakthrough Detection Time (Specimen 1,2,3) (Minutes)
16	Fentanyl Citrate Injection,	100mcg/2mL	>240 min.

Please note that the following drugs have low permeation times:
Carmustine: 26.6 minutes
Thiotepa: 56.0 minutes
***Warning** - Please do not use with Carmustine and Thiotepa

7. Technological characteristics Comparison for the proposed and predicate devices

Characteristics	Acceptance Criteria	Subject device: K222181 Iconic Blue Nitrile Glove- Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Small, Medium, Large, X-Large)	Predicate Device: K221269 Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Remarks
Product Code	NA	LZA, LZC, QDO, OPJ	LZA, LZC, QDO	Different
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over- the- counter 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 and Fentanyl Citrate as per ASTM D6978-05 (2019). Please note that the following drugs have low permeation times: Carmustine: 26.6 minutes, Thiotepa: 56.0 minutes Warning - Please do not use with Carmustine and Thiotepa	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 have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019). Please note that the following drugs have extremely low permeation times: Carmustine: 11.1 minutes, Thiotepa: 21.6 minutes. Warning: Do not use with Carmustine and Thiotepa.	same
Material used	Nitrile compound	Nitrile compound	Nitrile compound	same
Colour	N/A	Blue	Blue	same
Sterility	Sterile/Non-sterile	Non sterile	Non sterile	same
Single use	Single use	Single use	Single use	same
Dimensions	Overall Length (mm) Min 230mm	Overall Length (mm) Min 230mm	Overall Length (mm) Min 230mm	same
	Width (±10mm) Small - 80 Medium- 95 Large-110 X-large-120	Small - 80 Medium- 95 Large-110 X-large-120	Small - 80 Medium- 95 Large-110 X-large-120	same
	Thickness at Palm (mm) Min; 0.05 mm	Thickness at Palm (mm) Min; 0.05 mm	Thickness at Palm (mm) Min; 0.05 mm	same
	Thickness at Finger Tip (mm) Min 0.05 mm	Thickness at Finger Tip (mm) Min 0.05 mm	Thickness at Finger Tip (mm) Min 0.05 mm	same
Physical Properties	a.Before Aging			same
	Tensile Strength=14 MPa, min.	Tensile Strength=14 MPa, min.	Tensile Strength=14 MPa, min.	
	Ultimate Elongation= 500 % min	Ultimate Elongation= 500 % min	Ultimate Elongation= 500 % min	
	b. After Accelerated Aging			same
	Tensile Strength=14 MPa, min.	Tensile Strength=14 MPa, min.	Tensile Strength=14 MPa, min.	
	Ultimate Elongation= 400 % min	Ultimate Elongation= 400 % min	Ultimate Elongation= 400 % min	
Freedom from pinholes ASTM D5151	AQL 2.5 Inspection Level G-1	AQL 2.5	AQL 2.5	same
Residual Powder ASTM D6124- 06	< 2.0 mg/pc	< 2.0 mg/pc	< 2.0 mg/pc	same
	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of this study, the test article was a non- sensitizer.	Under the conditions of this study, the test article was a non- sensitizer.	same
	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of this study, the test article was a non-Irritant	Under the conditions of this study, the test article was a non-Irritant	same
	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-Cytotoxic to L929 cells	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells	Different
	ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Not induce acute systemic toxicity	Under the conditions of this study, there was no evidence of acute systemic toxicity.	same

Note: The difference between the subject device and predicate device is product code and ISO 10993-5 Biological evaluation of medical device – part 5: Test for in vitro cytotoxicity test results. The subject device meets the requirements of ASTM 6319 and non-cytotoxic to L929 cells, hence the subject device do not affect the safety and effectiveness of the device.

	TEST CHEMOTHERAPY DRUGS & Concentration	Subject device: Iconic Blue Nitrile Glove- Blue Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Small, Medium, Large, X-Large)	Predicate Device K221269 Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Remarks
		MINIMUM BREAKTHROUGH DETECTION TIME (Minutes)		
D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Carboplatin, 10 mg/ml (10,000 ppm)	>240 min.	>240 min.	same
	Carmustine, 3.3 mg/ml (3,300 ppm)	26.6	11.1	Different
	Cisplatin, 1 mg/ml (1,000 ppm)	>240 min.	>240 min.	same
	Cyclophosphamide, 20mg/ml (20,000 ppm)	>240 min.	>240 min.	same
	Dacarbazine, 10 mg/ml (10,000 ppm)	>240 min.	>240 min.	same
	Doxorubicin HCl, 2mg/ml (2,000 ppm)	>240 min.	>240 min.	same
	Etoposide, 20 mg/ml(20,000 ppm)	>240 min.	>240 min.	same
	Fluorouracil, 50 mg/ml(50,000 ppm)	>240 min.	>240 min.	same
	Methotrexate, 25 mg/ml(25,000 ppm)	>240 min.	>240 min.	same
	Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	>240 min.	same
	Mitoxantrone, 2 mg/ml(2,000 ppm)	>240 min.	>240 min.	same
	Oxaliplatin, 5 mg/ml(5,000 ppm)	>240 min.	>240 min.	same
	Paclitaxel, 6 mg/ml (6,000 ppm)	>240 min.	>240 min.	same
	Thiotepa, 10 mg/ml (10,000 ppm)	56	21.6	Different
	Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240 min.	>240 min.	same
	Busulfan 6mg/ml (6,000 ppm)	Not Tested	>240 min	Different
	Chloroquine 50mg/ml (50,000ppm)	Not Tested	>240 min	Different
	Cyclosporin 100 mg/ml (100,000 ppm)	Not Tested	>240 min	Different
	Cytarabine HCL, 100 mg/ml (100,000 ppm)	Not Tested	>240 min	Different
	Daunorubicin HCL, 5 mg/ml (5,000 ppm)	Not Tested	>240 min	Different
	Docetaxel, 10 mg/ml (10,000 ppm)	Not Tested	>240 min	Different
	Epirubicin HCL, 2 mg/ml (2,000 ppm)	Not Tested	>240 min	Different
	Fludarabine, 25 mg/ml (25,000 ppm)	Not Tested	>240 min	Different
	Gemcitabine, 38mg/ml (38,000ppm)	Not Tested	>240 min	Different
	Idarubicin HCL, 1mg/ml (1,000ppm)	Not Tested	>240 min	Different
	Ifosfamide, 50mg/ml (50,000ppm)	Not Tested	>240 min	Different
	Irinotecan, 20mg/ml (20,000ppm)	Not Tested	>240 min	Different
	Mechlorethamine HCI, 1mg/ml (1,000ppm)	Not Tested	>240 min	Different
	Melphalan, 5mg/ml (5,000ppm)	Not Tested	>240 min	Different
	Paraplatin, 10mg/ml (10,000ppm)	Not Tested	>240 min	Different
	Retrovir, 10mg/ml (10,000ppm)	Not Tested	>240 min	Different
	Rituximab, 10mg/ml (10,000ppm)	Not Tested	>240 min	Different
	Topotecan, 1mg/ml (1,000ppm)	Not Tested	>240 min	Different
	Trisenox, 1mg/ml (1,000ppm)	Not Tested	>240 min	Different
	Velcade, 1mg/ml 1,000ppm)	Not Tested	>240 min	Different
OPIOD DRUGS	TEST OPIOD DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm^2/minute)	Remarks
	Fentanyl Citrate Injection, 100mcg/2mL	>240 min	>240 min	same

Note: The assessment of resistance of Subject medical glove to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact are tested including the nine mandatory chemotherapy drugs as stated in the ASTM D6978. Both the devices meet the requirements of ASTM D6789. Hence, the differences do not affect the safety and effectiveness of the device. The subject device is labelled with the warnings and tested chemotherapy drugs list.

8. Summary of non-clinical testing results

Iconic Blue Nitrile Glove was tested and found in conformance with the following standards:

ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D6978-05 (Reapproved 2019)	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation on medical device Part 10: Test for irritation and Skin Irritation
ISO 10993-11	Biological evaluation of medical devices Part 11: Tests for systemic toxicity.

Test Methodology	**Purpose**	**Acceptance Criteria**	**Average Results**				**Final status**
ASTM D6319- 19	Size		Small	Medium	Large	X Large	
	Sterility	-	Non sterile	Non sterile	Non sterile	Non sterile	-
	Freedom from hole - ASTM D5151-19	AQL 2.5	Pass	Pass	Pass	Pass	Pass
		Overall Length (mm) Min 230mm.	234	234.61	240	244	Pass
	Dimensions – width, Length, Thickness AQL 4.0 Inspection level S-2	Width (±10mm) Small - 80 Medium- 95 Large-110 X- large-120	84.69	96.15	111.7	119.07	Pass
	Thickness at Palm & fingertip Min: 0.05 mm AQL 4.0 Inspection level S-2	Palm	0.09	0.09	0.1	0.1	Pass
		Fingertip	0.12	0.11	0.12	0.11	Pass
	Physical properties before aging, after accelerated aging AQL 4.0 Inspection level S-2	a. Before Aging					
		Tensile Strength=14 MPa, min.	21.12	20.07	20.53	21.82	Pass
		Ultimate Elongation= 500 % Min	900.24	836.57	839.47	841.89	Pass
		b. After Accelerated Aging					
		Tensile Strength=14 MPa, min.	23.54	20.35	21.96	21.2	Pass
		Ultimate Elongation= 400 % Min	878.09	813.34	851.65	815.63	Pass
	Powder-free Residue exceeds maximum limit - ASTM D6124-06	< 2.0 mg per glove	0.26	0.42	0.34	0.6	Pass
ISO 10993-5	Test for Invitro cytotoxicity	Non-Cytotoxic	Pass				
ISO 10993-10	Test for irritation and Skin Sensitization	Non-Sensitizing non-Irritating	Pass				
ISO 10993-11	Tests for acute systemic toxicity	Not induce acute systemic toxicity	Pass				

Test standard	S.No	TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm2/minute)	Other OBSERVATIONS
ASTM D6978-05(2019)	1	Carboplatin, 10mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	2	Carmustine, 3.3mg/ml (3,300 ppm)	26.6 (27.5,26.6,26.8)	0.5 (0.4,0.6,0.5)	Slight swelling and no degradation
	3	Cisplatin, 1 mg/ml(1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	4	Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	5	Dacarbazine, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	6	Doxorubicin HCI, 2mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	7	Etoposide, 20 mg/ml(20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	8	Fluorouracil, 50mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	9	Methotrexate, 25mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	10	Mitomycin C, 0.5mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and no degradation
	11	Mitoxantrone, 2mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	12	Oxaliplatin, 5 mg/ml(5,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	13	Paclitaxel, 6 mg/ml(6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	14	Thiotepa, 10 mg/ml(10,000 ppm)	56.0 (58.4,56.5,56.0)	1.1 (1.1,1.2,1.1)	Slight swelling and no degradation
	15	Vincristine Sulfate, 1mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
	16	**TEST OPIOD DRUGS**	**MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)**	**AVERAGE STEADY STATEPERM. RATE (Specimen1/2/3) (µg/cm2/minute)**	**Other OBSERVATIONS**
		Fentanyl Citrate Injection, 100mcg/2mL	>240 min	N/A	Slight swelling and no degradation

9. Summary of clinical Performance data

Not applicable - Clinical data was not used to assess performance of the subject device.

10. Conclusion

The Conclusions drawn from the non-Clinical tests demonstrate that the subject device- Iconic Blue Nitrile Glove – Tested for use with Chemotherapy Drugs & Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K221269.