February 6, 2025

Ever Global (Vietnam) Enterprise Corporation
Elizabeth Deng
U.S. Agent
Long Thanh Industrial Zone
Taman Village, Dong Nai Province 810000
Vietnam

Re: K244034
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate and Xylazine
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 27, 2024
Received: December 30, 2024

Dear Elizabeth Deng:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244034

Device Name
Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate and Xylazine

Indications for Use *(Describe)*
A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs, fentanyl citrate, and xylazine in accordance with ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical gloves to Permeation by Chemotherapy Drugs.

Tested Chemotherapy and Other Liquid Hazardous Drug	Concentration(mg/ml)	Minimum Breakthrough Detection Time(Min)
01 Arsenic Trioxide	1.0	> 240
02 Azacitidine (Vidaza)	25.0	> 240
03 Bendamustine HCl	5.0	> 240
04 Bleomycin Sulfate	15.0	> 240
05 Bortezomib (Velcade)	1.0	> 240
06 Busulfan	6.0	> 240
07 Carboplatin	10.0	> 240
08 Carfilzomib	2.0	> 240
09 Carmustine (BCNU)	3.3	21.5
10 Cetuximab (Erbitux)	2.0	> 240
11 Chloroquine	50.0	> 240
12 Cisplatin	1.0	> 240
13 Cladribine	1.0	> 240
14 Cyclophosphamide	20.0	> 240
15 Cyclosporine A	100.0	> 240
16 Cytarabine	100.0	> 240
17 Cytovene (Ganciclovir)	10.0	> 240
18 Dacarbazine	10.0	> 240
19 Daunorubicin	5.0	> 240
20 Decitabine	5.0	> 240
21 Docetaxel	10.0	> 240
22 Doxorubicin Hydrochloride	2.0	> 240
23 Epirubicin (Ellence)	2.0	> 240
24 Etoposide	20.0	> 240
25 Fludarabine	25.0	> 240
26 Fluorouracil	50.0	> 240
27 Fulvestrant	50.0	> 240
28 Gemcitabine	38.0	> 240
29 Idarubicin	1.0	> 240
30 Ifosfamide	50.0	> 240
31 Irinotecan	20.0	> 240
32 Mechlorethamine HCl	1.0	> 240
33 Melphalan	5.0	> 240
34 Methotrexate	25.0	> 240
35 Mesna	100.0	> 240
36 Mitomycin C	0.5	> 240

37 Mitoxantrone	2.0	> 240
38 Oxaliplatin	5.0	> 240
39 Paclitaxel	6.0	> 240
40 Paraplatin	10.0	> 240
41 Pemetrexed	25.0	> 240
42 Pertuzumab	30.0	> 240
43 Raltitrexed	0.5	> 240
44 Retrovir	10.0	> 240
45 Rituximab	10.0	> 240
46 Temsirolimus	25.0	> 240
47 Thiotepa	10.0	13.6
48 Topotecan HCl	1.0	> 240
49 Trastuzumab	21.0	> 240
50 Triclosan	2.0	> 240
51 Trisenox	1.0	> 240
52 Vinblastine	1.0	> 240
53 Vincristine Sulfate	1.0	> 240
54 Vinorelbine	10.0	> 240
55 Zoledronic Acid	0.8	> 240
56 Fentanyl Citrate	100.0 mcg/ 2.0 ml	> 240

Warning: do not use with Carmustine and Thiotepa.
The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU)	3.3 mg/ml	21.5 minutes
Thiotepa	10.0 mg/ml	13.6 minutes

Xylazine Permeation Resistance Claim - Under the testing conditions of ASTM D6978-05, Xylazine HCl Injection (100.0 mg/ml) was found to have no breakthrough detected for up to 240 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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510(k) SUMMARY

0.0 Summary Preparation Date: February 5, 2025

1.0 Submitter:

Submitter's name:	Ever Global (Vietnam) Enterprise Corporation
Submitter's address:	Long Thanh Industrial Zone, Taman Village, Dong Nai Province, Long Thanh District, VN 810000
Phone number:	84-61-3514022
Fax number:	84-61-3514023
Name of contact person:	Jerry Lin

2.0 US Agent:

US Representative Name:	Elizabeth Deng
Company Address:	5748 Eaglewood Place Rancho Cucamonga, California Rancho Cucamonga, CA 91739
Telephone Number:	909 4659188
Contact Email Address:	baxianunited48@yahoo.com

3.0 Name of the Device

Proprietary/Trade name:	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine
Common Name:	Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs And Fentanyl Citrate And Xylazine
Classification Name:	Non-powdered Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC, QDO, OPJ
510(K) Number:	K244034

4.0 Predicate device

Device Name:	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate
Company name:	Ever Global (Vietnam) Enterprise Corporation
510(K) Number:	K193555

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5.0 Device Description:

"Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine" is a patient examination glove made from nitrile compound, non-sterile (as per 21 CFR 880.6250, Class I). The principle operation of this medical device is to provide single use barrier protection for the wearer and the device meets the specifications for Barrier Protection and tensile properties as defined in ASTM D6319-19, Standard specification for Nitrile Examination Gloves.

6.0 Device Indications for use:

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs, fentanyl citrate, and xylazine in accordance with ASTM D6978-05 standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs.

Table 1 – Tested for use with 57 chemotherapy and other liquid hazardous drugs

No.	Tested Chemotherapy and Other Liquid Hazardous Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1	Arsenic Trioxide (1.0 mg/ml)	>240
2	Azacitidine (Vidaza) (25.0 mg/ml)	>240
3	Bendamustine HCl (5.0 mg/ml)	>240
4	Bleomycin Sulfate (15.0 mg/ml)	>240
5	Bortezomib (Velcade) (1.0 mg/ml)	>240
6	Busulfan (6.0 mg/ml)	>240
7	Carboplatin (10.0 mg/ml)	>240
8	Carfilzomib (2.0 mg/ml)	>240
9	Carmustine (BCNU), (3.3 mg/ml)	21.5
10	Cetuximab (Erbitux) (2.0 mg/ml)	>240
11	Chloroquine (50.0 mg/ml)	>240
12	Cisplatin (1.0 mg/ml)	>240
13	Cladribine (1.0 mg/ml)	>240
14	Cyclophosphamide (20.0 mg/ml)	>240
15	Cyclosporin A (100.0 mg/ml)	>240
16	Cytarabine (100.0 mg/ml)	>240
17	Cytovene (Ganciclovir) (10.0 mg/ml)	>240

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18	Dacarbazine (DTIC), (10.0 mg/ml)	>240
19	Daunorubicin (5.0 mg/ml)	>240
20	Decitabine (5.0 mg/ml)	>240
21	Docetaxel (10.0 mg/ml)	>240
22	Doxorubicin Hydrochloride (2.0mg/ml)	>240
23	Epirubicin (Ellence) (2.0 mg/ml)	>240
24	Etoposide, (20.0 mg/ml)	>240
25	Fludarabine (25.0 mg/ml)	>240
26	Fluorouracil, (50.0 mg/ml)	>240
27	Fulvestrant (50.0 mg/ml)	>240
28	Gemcitabine (38.0 mg/ml)	>240
29	Idaribicin (1.0 mg/ml)	>240
30	Ifosfamide (50.0 mg/ml)	>240
31	Irinotecan (20.0 mg/ml)	>240
32	Mechlorethamine HCl (1.0 mg/ml)	>240
33	Melphalan (5.0 mg/ml)	>240
34	Methotrexate (25 mg/ml)	>240
35	Mesna (100 mg/ml)	>240
36	Mitomycin C (0.5 mg/ml)	>240
37	Mitoxantrone (2.0 mg/ml)	>240
38	Oxaliplatin (5.0 mg/ml)	>240
39	Paclitaxel (Taxol), (6.0 mg/ml)	>240
40	Paraplatin (10.0 mg/ml)	>240
41	Pemetrexed (25.0 mg/ml)	>240
42	Pertuzumab (30.0 mg/ml)	>240
43	Raltitrexed (0.5 mg/ml)	>240
44	Retrovir (10.0 mg/ml)	>240
45	Rituximab (10.0 mg/ml)	>240
46	Temsirolimus (25.0 mg/ml)	>240
47	Thiotepa (10.0 mg/ml)	13.6
48	Topotecan HCl (1.0 mg/ml)	>240

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49	Trastuzumab (21.0 mg/ml)	>240
50	Triclosan (2.0 mg/ml)	>240
51	Trisenox (1.0 mg/ml)	>240
52	Vinblastine (1.0 mg/ml)	>240
53	Vincristine Sulfate (1.0 mg/ml)	>240
54	Vinorelbine (10.0 mg/ml)	>240
55	Zoledronic Acid (0.8 mg/ml)	>240
56	Fentanyl Citrate Injection (100.0mcg/2.0ml)	>240

Warning: do not use with Carmustine and Thiotepa.

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	21.5 minutes
Thiotepa, 10.0 mg/ml	13.6 minutes

Xylazine Permeation Resistance Claim - Under the testing conditions of ASTM D6978-05, Xylazine HCl Injection (100.0 mg/ml) was found to have no breakthrough detected for up to 240 minutes.

7.0 Comparison of device technological characteristics:

Device Characteristic	Predicate Device	Subject Device	Comparison
Product Name	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate and Xylazine	similar
510(K) No.	K193555	K244034	n/a
Product Owner	Ever Global (Vietnam) Enterprise Corporation	Ever Global (Vietnam) Enterprise Corporation	same
Product Code	LZA, LZC, QDO	LZA, LZC, QDO, OPJ	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Indications for Use	The nitrile powder free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. In addition,	The nitrile powder free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. In addition,	similar

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	these gloves were tested for use with chemotherapy drugs and fentanyl citrate in accordance with ASTM D6978-05 standard practice for assessment of medical gloves to permeation by chemotherapy drugs.	these gloves were tested for use with chemotherapy drugs and fentanyl citrate and xylazine in accordance with ASTM D6978-05 standard practice for assessment of medical gloves to permeation by chemotherapy drugs.	
Power free	Yes	Yes	same
Size	XS/S/M/L/XL	XS/S/M/L/XL	same
Over-The-Counter Use	Yes (21 CFR 801 Subpart C)	Yes (21 CFR 801 Subpart C)	same
Single Use	Yes	Yes	same
Non-Sterile	Yes	Yes	same
Shelf life	No	No	same
Dimensions-Length	Complies with ASTM D6319-10 Short cuff ≥230mm Long cuff ≥300mm	Complies with ASTM D6319-19 Short cuff ≥230mm Long cuff ≥300mm	same
Dimensions - Palm Width	Complies with ASTM D6319-10 XS: 70 ± 10 mm; S: 80 ± 10 mm; M: 95 ± 10 mm; L: 110 ± 10 mm; XL: 120 ± 10 mm	Complies with ASTM D6319-19 XS: 70 ± 10 mm; S: 80 ± 10 mm; M: 95 ± 10 mm; L: 110 ± 10 mm; XL: 120 ± 10 mm	same
Dimensions - Thickness	Complies with ASTM D6319-10 Palm ≥0.05 mm; Finger ≥0.05 mm Cuff ≥ 0.05 mm	Complies with ASTM D6319-19 Palm ≥0.05 mm; Finger ≥0.05 mm Cuff ≥ 0.05 mm	same
Physical Properties	Complies with ASTM D6319-10 Tensile Strength Before aging≥14MPa After aging ≥14MPa	Complies with ASTM D6319-19 Tensile Strength Before aging≥14MPa After aging ≥14MPa	same
	Complies with ASTM D6319-10 Elongation: Before Aging: ≥500% After Aging: ≥400%	Complies with ASTM D6319-19 Elongation: Before Aging: ≥ 500% After Aging: ≥400%	same
Residual powder	Complies with ASTM D6319-10 < 2mg per glove	Complies with ASTM D6319-19 < 2mg per glove	same
Freedom from Holes	In accordance with ASTM D6319-10 (G-1 with AQL 2.5)	In accordance with ASTM D6319-19 (G-1 with AQL 2.5)	same
Biocompatibility	AAMI/ANSI/ISO 10993-10 & AAMI/ANSI/ISO 10993-5 Passes Not a skin irritant, Not a skin sensitizer & No cytotoxicity reaction	AAMI/ANSI/ISO 10993-10 & AAMI/ANSI/ISO 10993-5 Passes Not a skin irritant, Not a skin sensitizer & No cytotoxicity reaction	same
Resistance of Gloves to Permeation by Chemotherapy Drugs	no. / Test Chemotherapy Drug and Concentration / Minimum Breakthrough Detection Time (Min.) 1 / Arsenic Trioxide (1.0 mg/ml) / >240	no. / Test Chemotherapy Drug and Concentration / Minimum Breakthrough Detection Time (Min.) 1 / Arsenic Trioxide (1.0 mg/ml) / >240	similar

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	2	Azacitidine (Vidaza) (25.0 mg/ml)	>240	2	Azacitidine (Vidaza) (25.0 mg/ml)	>240
	3	Bendamustine HCl (5.0 mg/ml)	>240	3	Bendamustine HCl (5.0 mg/ml)	>240
	4	Bleomycin Sulfate (15.0 mg/ml)	>240	4	Bleomycin Sulfate (15.0 mg/ml)	>240
	5	Bortezomib (Velcade) (1.0 mg/ml)	>240	5	Bortezomib (Velcade) (1.0 mg/ml)	>240
	6	Busulfan (6.0 mg/ml)	>240	6	Busulfan (6.0 mg/ml)	>240
	7	Carboplatin (10.0 mg/ml)	>240	7	Carboplatin (10.0 mg/ml)	>240
	8	Carfilzomib (2.0 mg/ml)	>240	8	Carfilzomib (2.0 mg/ml)	>240
	9	Carmustine (BCNU), (3.3 mg/ml)	6.2	9	Carmustine (BCNU), (3.3 mg/ml)	21.5
	10	Cetuximab (Erbitux) (2.0 mg/ml)	>240	10	Cetuximab (Erbitux) (2.0 mg/ml)	>240
	11	Chloroquine (50.0 mg/ml)	>240	11	Chloroquine (50.0 mg/ml)	>240
	12	Cisplatin (1.0 mg/ml)	>240	12	Cisplatin (1.0 mg/ml)	>240
	13	Cladribine (1.0 mg/ml)	>240	13	Cladribine (1.0 mg/ml)	>240
	14	Cyclophosphamide (20.0 mg/ml)	>240	14	Cyclophosphamide (20.0 mg/ml)	>240
	15	Cyclosporin A (100.0 mg/ml)	>240	15	Cyclosporin A (100.0 mg/ml)	>240
	16	Cytarabine (100.0 mg/ml)	>240	16	Cytarabine (100.0 mg/ml)	>240
	17	Cytovene (Ganciclovir) (10.0 mg/ml)	>240	17	Cytovene (Ganciclovir) (10.0 mg/ml)	>240
	18	Dacarbazine (DTIC), (10.0 mg/ml)	>240	18	Dacarbazine (DTIC), (10.0 mg/ml)	>240
	19	Daunorubicin (5.0 mg/ml)	>240	19	Daunorubicin (5.0 mg/ml)	>240
	20	Decitabine (5.0 mg/ml)	>240	20	Decitabine (5.0 mg/ml)	>240
	21	Docetaxel (10.0 mg/ml)	>240	21	Docetaxel (10.0 mg/ml)	>240
	22	Doxorubicin Hydrochloride (2.0mg/ml)	>240	22	Doxorubicin Hydrochloride (2.0mg/ml)	>240
	23	Epirubicin (Ellence) (2.0 mg/ml)	>240	23	Epirubicin (Ellence) (2.0 mg/ml)	>240
	24	Etoposide, (20.0 mg/ml)	>240	24	Etoposide, (20.0 mg/ml)	>240
	25	Fludarabine (25.0 mg/ml)	>240	25	Fludarabine (25.0 mg/ml)	>240
	26	Fluorouracil, (50.0 mg/ml)	>240	26	Fluorouracil, (50.0 mg/ml)	>240
	27	Fulvestrant (50.0 mg/ml)	>240	27	Fulvestrant (50.0 mg/ml)	>240
	28	Gemcitabine (38.0 mg/ml)	>240	28	Gemcitabine (38.0 mg/ml)	>240
	29	Idaribicin (1.0 mg/ml)	>240	29	Idaribicin (1.0 mg/ml)	>240

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	30	Ifosfamide (50.0 mg/ml)	>240	30	Ifosfamide (50.0 mg/ml)	>240
	31	Irinotecan (20.0 mg/ml)	>240	31	Irinotecan (20.0 mg/ml)	>240
	32	Mechlorethamine HCl (1.0 mg/ml)	>240	32	Mechlorethamine HCl (1.0 mg/ml)	>240
	33	Melphalan (5.0 mg/ml)	>240	33	Melphalan (5.0 mg/ml)	>240
	34	Methotrexate (25 mg/ml)	>240	34	Methotrexate (25 mg/ml)	>240
	35	Mesna (100 mg/ml)	>240	35	Mesna (100 mg/ml)	>240
	36	Mitomycin C (0.5 mg/ml)	>240	36	Mitomycin C (0.5 mg/ml)	>240
	37	Mitoxantrone (2.0 mg/ml)	>240	37	Mitoxantrone (2.0 mg/ml)	>240
	38	Oxaliplatin (5.0 mg/ml)	>240	38	Oxaliplatin (5.0 mg/ml)	>240
	39	Paclitaxel (Taxol), (6.0 mg/ml)	>240	39	Paclitaxel (Taxol), (6.0 mg/ml)	>240
	40	Paraplatin (10.0 mg/ml)	>240	40	Paraplatin (10.0 mg/ml)	>240
	41	Pemetrexed (25.0 mg/ml)	>240	41	Pemetrexed (25.0 mg/ml)	>240
	42	Pertuzumab (30.0 mg/ml)	>240	42	Pertuzumab (30.0 mg/ml)	>240
	43	Raltitrexed (0.5 mg/ml)	>240	43	Raltitrexed (0.5 mg/ml)	>240
	44	Retrovir (10.0 mg/ml)	>240	44	Retrovir (10.0 mg/ml)	>240
	45	Rituximab (10.0 mg/ml)	>240	45	Rituximab (10.0 mg/ml)	>240
	46	Temsirolimus (25.0 mg/ml)	>240	46	Temsirolimus (25.0 mg/ml)	>240
	47	Thiotepa (10.0 mg/ml)	13.6	47	Thiotepa (10.0 mg/ml)	13.6
	48	Topotecan HCl (1.0 mg/ml)	>240	48	Topotecan HCl (1.0 mg/ml)	>240
	49	Trastuzumab (21.0 mg/ml)	>240	49	Trastuzumab (21.0 mg/ml)	>240
	50	Triclosan (2.0 mg/ml)	>240	50	Triclosan (2.0 mg/ml)	>240
	51	Trisenox (1.0 mg/ml)	>240	51	Trisenox (1.0 mg/ml)	>240
	52	Vinblastine (1.0 mg/ml)	>240	52	Vinblastine (1.0 mg/ml)	>240
	53	Vincristine Sulfate (1.0 mg/ml)	>240	53	Vincristine Sulfate (1.0 mg/ml)	>240
	54	Vinorelbine (10.0 mg/ml)	>240	54	Vinorelbine (10.0 mg/ml)	>240
	55	Zoledronic Acid (0.8 mg/ml)	>240	55	Zoledronic Acid (0.8 mg/ml)	>240
	56	Fentanyl Citrate Injection, (100 mcg/2ml)	>240	56	Fentanyl Citrate Injection, (100 mcg/2ml)	>240
				57	Xylazine HCl (100 mg/ml)	>240

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510(k) SUMMARY

8.0 Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine met the predetermined acceptance criteria. No new safety or performance issues were raised during testing:

Test	Test Method	Purpose	Acceptance Criteria	Results
Dimension	ASTM D6319-19	Determine the geometrical dimension of gloves	Length: Short cuff: ≥230mm Long cuff: ≥300mm Thickness: Palm: ≥ 0.05 mm Finger: ≥ 0.05 mm Cuff: ≥ 0.05 mm Palm Width: XS: 70 ± 10 mm S: 80 ± 10 mm M: 95± 10 mm L: 110 ± 10 mm XL: 120 ± 10 mm	Pass
Freedom from holes (Water leak)	21 CFR 800.20. & ASTM D5151-19	Detect the holes on the gloves.	G-I/ AQL 2.5	Pass
Tensile strength (Before aging/ After aging)	ASTM D6319-19	Evaluate the tensile (tenson) properties of the gloves. In addition, it also determines the influence of elevated temperature on the physical properties of gloves.	Before Aging: ≥14MPa After Aging: ≥14MPa	Pass
Elongation (Before aging/ After aging)	ASTM D6319-19		Before Aging: ≥500% After Aging: ≥400%	Pass
Powder Residual	ASTM D6319-19	Determine the average powder mass found on the gloves	< 2mg per glove	Pass
Biocompatibility-cytotoxicity	AAMI/ANSI/ISO 10993-5	Determine the cytotoxicity potential of glove	No *in vitro* cytotoxic as described in ISO 10993-5	Pass
Biocompatibility-Skin Sensitization and Irritation	AAMI/ANSI/ISO 10993-10	Determine the potential of glove to promote skin sensitization after repeated applications	No dermal reactions indicative of delayed contact hypersensitivity	Pass
		Determine the potential of gloves to promote skin irritation after repeated applications.	No skin irritation, cumulative irritation index to be 0.	Pass

510(k) SUMMARY

Resistance of Gloves to Permeation by Chemotherapy Drugs	ASTM D6978-05	Assessment of medical gloves to permeation by chemotherapy drugs.	The resistance of our device to permeation were challenged against 57 liquid hazardous drugs	Pass

9.0 Assessment of Clinical Performance Data:

Clinical data is not needed for this type of device.

10.0 Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine is as safe, as effective, and performs as well as or better than the legally marketed device, K193555.