June 4, 2020

Ever Global (Vietnam) Enterprise Corp
% Elizabeth Deng
U.S. Representative
Elizabeth Deng
5748 Eaglewood Place
Ranch Cucamonga, California 91730

Re: K193555
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Blue Color, 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: LZC, LZA, QDO
Dated: April 29, 2020
Received: May 5, 2020

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 (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,

CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193555

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

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 and fentanyl citrate in accordance with ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical gloves to Permeation by Chemotherapy Drugs.

Test Chemotherapy 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	6.2
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 mg/ml)	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

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	6.2 minutes
Thiotepa	10.0 mg/ml	13.6 minutes

Fentanyl Permeation Resistance Claim - Under the testing conditions of ASTM D6978-05, Fentanyl Citrate Injection (100mcg/2mL) was found to have no breakthrough detected 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

K193555

1.0 Submitter:

Submitter's name :	Ever Global (Vietnam) Enterprise Corp.
Submitter's address :	Long Thanh Industrial Zone Taman Village Dong Nai Province, VN 810000
Phone number :	84-61-3514022
Fax number :	84 -61-3514023
Name of contact person:	Jerry Lin
Summary Preparation Date:	May 27th,2020

2.0 US Agent:

US representative name:	Elizabeth Deng
Company address:	5748 Eaglewood Place Rancho Cuamonga, California Rancho Cucamonga , CA 91739
Telephone number:	909 4659188
Contact email:	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
Common Name:	Nitrile Examination Gloves
Classification Name:	Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC, QDO

4.0 Predicate device

Device Name:	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs
Company name:	Ever Global (Vietnam) Enterprise Corp.
510(K) Number:	K190403

5.0 Device Description:

"Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate" 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 D6319-10, Standard specification for Nitrile Examination Gloves.

6.0 Indication for use:

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate

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 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 55 chemotherapy drugs.

No.	Test Chemotherapy 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)	6.2
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	Cyclosporine A (100.0 mg/ml)	> 240
16	Cytarabine (100.0 mg/ml)	> 240
17	Cytovene (Ganciclovir) (10.0 mg/ml)	> 240
18	Dacarbazine (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 (2.0 mg/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	Idarubicin (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 (6.0mg/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
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

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	6.2 minutes
Thiotepa, 10.0 mg/ml	13.6 minutes

Fentanyl Permeation Resistance Claim - Under the testing conditions of ASTM D6978-05, Fentanyl Citrate Injection (100mcg/2mL) was found to have no breakthrough detected for up to 240 minutes.

7.0 Comparison of Technological characteristics between the predicate and subject devices:

Table 2 Comparison of 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	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate	similar
510(K) No.	K190403	K193555	N/A
Product Owner	Ever Global (Vietnam) Enterprise Corporation	Ever Global (Vietnam) Enterprise Corporation	same
Product Code	LZA, LZC	LZA, LZC, QDO	similar
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Intended 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, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	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, 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.	similar
Powder free	Yes	Yes	same
Size	Small/ Medium/Large/X Large	X Small/ Small/Medium/Large/X Large	X Small is additional.
Single Use	YES	YES	same
Non-Sterile	No	No	same
Dimensions-Length	Complies with ASTM D6319-10 230 mm min.	Short cuff ≥230mm Long cuff ≥300mm	Long cuff is additional.
Dimensions - Palm Width	Complies with ASTM D6319-10	Complies with ASTM D6319-10	Similar. X Small is additional.
	Small 80 ±10 Medium 95±10 Large 110 ±10 X large 120 ±10	X Small 70±10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	

Dimensions - Thickness	Complies with ASTM D6319-10 Palm 0.05mm min. Finger 0.05 mm min. Cuff 0.05 mm min	Complies with ASTM D6319-10 Palm 0.05mm min. Finger 0.05 mm min. Cuff 0.05 mm min	same
Physical Properties	Tensile Strength: Before Aging 14 MPa, min. After Aging 14 MPa, min.	Tensile Strength: Before Aging 14 MPa, min. After Aging 14 MPa, min.	same
	Elongation: Before Aging 500% min. After Aging 400% min.	Elongation: Before Aging 500% min. After Aging 400% min.	same
Residual powder	Complies with ASTM D6319-10 ＜ 2mg per glove	Complies with ASTM D6319-10 ＜ 2mg per glove	same
Freedom from Holes	In accordance with ASTM D6319-10 and ASTM D5151- 06 (reapproved 2015), G-1, AQL2.5	In accordance with ASTM D6319-10 and ASTM D5151-06 (reapproved 2015), G-1, AQL 2.5	same
Biocompatibility	AAMI/ANSI/ISO 10993-10 Passes Not a skin irritant & Not a skin sensitizer	AAMI/ANSI/ISO 10993-10 & AAMI/ANSI/ISO 10993-5 Passes Not a skin irritant, Not a skin sensitizer & No cytotoxicity reaction	same

Chemotherapy drugs tested	Breakthrough Detection Time in Minutes			Comparison
Device Characteristic	Predicate device K190403	Subject Device K193555		
		Short Cuff	Long Cuff	
Arsenic Trioxide (1.0 mg/ml)	-	> 240		Different
Azacitidine (Vidaza) (25.0 mg/ml)	-	> 240		Different
Bendamustine HCl (5.0 mg/ml)	-	> 240		Different
Bleomycin Sulfate (15.0 mg/ml)	-	> 240		Different
Bortezomib (Velcade) (1.0 mg/ml)	-	> 240		Different
Busulfan (6.0 mg/ml)	-	> 240		Different
Carboplatin (10.0 mg/ml)	-	> 240		Different
Carfilzomib (2.0 mg/ml)	-	> 240		Different
Carmustine (BCNU), (3.3 mg/ml)	6.2	21.5	37.5	Similar
Cetuximab (Erbitux) (2.0 mg/ml)	-	> 240		Different
Chloroquine (50.0 mg/ml)	-	> 240		Different
Cisplatin (1.0 mg/ml)	> 240	> 240		Same
Cladribine (1.0 mg/ml)	-	> 240		Different
Cyclophosphamide (20.0 mg/ml)	> 240	> 240		Same
Cyclosporin A (100.0 mg/ml)	-	> 240		Different
Cytarabine (100.0 mg/ml)	-	> 240		Different
Cytovene (Ganciclovir) (10.0 mg/ml)	-	> 240		Different

Dacarbazine (DTIC), (10.0 mg/ml)	> 240	> 240		Same
Daunorubicin (5.0 mg/ml)	-	> 240		Different
Decitabine (5.0 mg/ml)	-	> 240		Different
Docetaxel (10.0 mg/ml)	-	> 240		Different
Doxorubicin Hydrochloride (2.0mg/ml)	> 240	> 240		Same
Epirubicin (Ellence) (2.0 mg/ml)	-	> 240		Different
Etoposide, (20.0 mg/ml)	> 240	> 240		Same
Fludarabine (25.0 mg/ml)	-	> 240		Different
Fluorouracil, (50.0 mg/ml)	> 240	> 240		Same
Fulvestrant (50.0 mg/ml)	-	> 240		Different
Gemcitabine (38.0 mg/ml)	-	> 240		Different
Idaribicin (1.0 mg/ml)	-	> 240		Different
Ifosfamide (50.0 mg/ml)	-	> 240		Different
Irinotecan (20.0 mg/ml)	-	> 240		Different
Mechlorethamine HCl (1.0 mg/ml)	-	> 240		Different
Melphalan (5.0 mg/ml)	-	> 240		Different
Methotrexate (25 mg/ml)	-	> 240		Different
Mesna (100 mg/ml)	-	> 240		Different
Mitomycin C (0.5 mg/ml)	-	> 240		Different
Mitoxantrone (2.0 mg/ml)	-	> 240		Different
Oxaliplatin (5.0 mg/ml)	-	> 240		Different
Paclitaxel (Taxol), (6.0 mg/ml)	> 240	> 240		Same
Paraplatin (10.0 mg/ml)	-	> 240		Different
Pemetrexed (25.0 mg/ml)	-	> 240		Different
Pertuzumab (30.0 mg/ml)	-	> 240		Different
Raltitrexed (0.5 mg/ml)	-	> 240		Different
Retrovir (10.0 mg/ml)	-	> 240		Different
Rituximab (10.0 mg/ml)	-	> 240		Different
Temsirolimus (25.0 mg/ml)	-	> 240		Different
Thiotepa (10.0 mg/ml)	38.8	23.1	13.6	Similar
Topotecan HCl (1.0 mg/ml)	-	> 240		Different
Trastuzumab (21.0 mg/ml)	-	> 240		Different
Triclosan (2.0 mg/ml)	-	> 240		Different
Trisenox (1.0 mg/ml)	-	> 240		Different
Vinblastine (1.0 mg/ml)	-	> 240		Different

Vincristine Sulfate (1.0 mg/ml)	-	> 240	Different
Vinorelbine (10.0 mg/ml)	-	> 240	Different
Zoledronic Acid (0.8 mg/ml)	-	> 240	Different
Fentanyl Permeation Resistance			
Fentanyl Citrate Injection, (100 mcg/2ml)	-	> 240	Different

8.0 Summary of Non-clinical testing results:

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table 3 Summary of the Technological Characteristics

Characteristics	Standard			
Dimension	ASTM standard D 6319-10(Reapproved 2015)			
	Length	Short cuff Long cuff	≥230mm ≥300mm	
	Width	X Small Small	70 ± 10 mm 80 ± 10 mm	
		Medium	95 ± 10 mm	
		Large	110 ± 10 mm	
		X large	120 ± 10 mm	
	Thickness	Finger tip	≥0.05mm	
		Palm Cuff	≥0.05mm ≥0.05mm	
Physical Properties	ASTM standard D 6319-10(Reapproved 2015)			
	Tensile strength (Before aging)			≥14MPa
	Tensile strength (After aging)			≥14MPa
	Elongated rate (Before aging)			≥500%
	Elongated rate (After aging)			≥400%
Freedom from pinholes	21 CFR 800.20 ASTM standard D 6319-10(Reapproved 2015) Test method in accordance with ASTM D5151-06(Reapproved 2015)			Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D6319-10(Reapproved 2015) Test method in accordance with D6124-06(Reaffirmation 2011)			< 2 mg/glove
Biocompatibility	Primary Skin Irritation in rabbits	Pass Under the conditions of the study, the subject device is not a primary skin irritant.		
	Dermal sensitization in the guinea pig	Pass Under the conditions of the study, the subject device is not a primary skin sensitizer.		
	In vitro cytotoxicity	Pass Under the conditions of the study, the subject device is not shown cytotoxicity.		

The following bench testing was conducted for the Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate made by Ever Global (Vietnam) Enterprise Corp:

- Dimension per ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application

- Tensile strength(Before aging/After aging) and Elongation(Before aging/After aging) per ASTM D6319-10(Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application
- Water leak test on pinhole per ASTM D6319-10(Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application and per 21 CFR 800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects;adulteration.
- Powder Residual tests per ASTM D6319-10(Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application.
- Biocompatibility test per ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity & ISO 10993-10: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
- Assessment Of Resistance To Permeation By Chemotherapy Drugs And Fentanyl Citrate per ASTM D6978-05(R 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

9.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device the Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K190403.