March 27, 2024

Ever Growth (Vietnam) Corporation Limited
Deng Elizabeth
U.S. Agent
Long Khanh Industrial Zone,
Binh Loc Commune,
Long Khanh City, Dong Nai 76461
Vietnam

Re: K234097
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, Natural 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: LZA, LZC, OPJ, QDO
Dated: December 1, 2023
Received: December 26, 2023

Dear Deng Elizabeth:

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.

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,

Bifeng Qian -S

Bifeng Qian, M.D, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K234097

Device Name
Disposable Powder Free Nitrile Examination Glove, Natural Blue Color, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
A non-powdered 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. In addition, these gloves were tested respectively 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.

| No. | Test Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Min.)* |
|---|---|---|
| 1 | Bleomycin Sulfate 15.0 mg/ml | > 240 |
| 2 | Busulfan 6.0 mg/ml | > 240 |
| 3 | Carboplatin 10.0 mg/ml | > 240 |
| 4 | Carmustine (BCNU) 3.3 mg/ml | 59.4 |
| 5 | Chloroquine 50.0 mg/ml | > 240 |
| 6 | Cisplatin 1 mg/ml | > 240 |
| 7 | Cyclophosphamide 20 mg/ml | > 240 |
| 8 | Cyclosporin A 100.0 mg/ml | > 240 |
| 9 | Cytarabine 100.0 mg/ml | > 240 |
| 10 | Dacarbazine (DTIC), 10.0 mg/ml | > 240 |
| 11 | Daunorubicin 5.0 mg/ml | > 240 |
| 12 | Docetaxel 10.0 mg/ml | > 240 |
| 13 | Doxorubicin Hydrochloride 2.0 mg/ml | > 240 |
| 14 | Epirubicin 2.0 mg/ml | > 240 |
| 15 | Etoposide (Toposar) 20.0 mg/ml | > 240 |
| 16 | Fludarabine 25.0 mg/ml | > 240 |
| 17 | Fluorouracil 50.0 mg/ml | > 240 |
| 18 | Gemcitabine 38.0 mg/ml | > 240 |
| 19 | Idaribicin 1.0 mg/ml | > 240 |
| 20 | Ifosfamide 50.0 mg/ml | > 240 |
| 21 | Irinotecan 20.0 mg/ml | > 240 |
| 22 | Mechlorethamine HCl 1.0 mg/ml | > 240 |
| 23 | Melphalan 5.0 mg/ml | > 240 |
| 24 | Methotrexate 25 mg/ml | > 240 |
| 25 | Mitomycin C 0.5 mg/ml | > 240 |
| 26 | Mitoxantrone 2.0 mg/ml | > 240 |
| 27 | Oxaliplatin 2.0 mg/ml | > 240 |
| 28 | Paclitaxel (Taxol), 6.0 mg/ml | > 240 |
| 29 | Paraplatin 10 mg/ml | > 240 |
| 30 | Retrovir 10 mg/ml | > 240 |
| 31 | Rituximab 10 mg/ml | > 240 |
| 32 | Thiotepa, 10.0 mg/ml | 118.5 |
| 33 | Topotecan HCl 1.0 mg/ml | > 240 |
| 34 | Trisonex 1.0 mg/ml | > 240 |
| 35 | Velcade (Bortezomib) 1.0 mg/ml | > 240 |
| 36 | Vincristine 1.0 mg/ml | > 240 |

Fentanyl Citrate Test

| | |
|---|---|
| Fentanyl Citrate Injection 100 mcg/2ml | >240 |
| Thiotepa and Carmustine have low permeation times | |

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
# K234097

**0.0 Summary Preparation Date:** March 23, 2024

**1.0 Submitter:**

| | |
|---|---|
| Submitter's name: | EVER GROWTH (VIETNAM) CORPORATION LIMITED |
| Submitter's address: | Long Khanh Industrial Zone, Binh Loc Commune, Long Khanh City, Dong Nai, VN 76461 |
| 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<br>Rancho Cucamonga, California<br>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, Natural Blue Color, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate |
| Common Name: | Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate |
| Classification Name: | Non-powdered Patient Examination Glove |
| Device Classification: | Class I |
| Regulation Number: | 21 CFR 880.6250 |
| Product Code: | LZA, LZC, OPJ, QDO |

**4.0 Predicate device**

| | |
|---|---|
| Device Name: | Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested for Use with Chemotherapy Drugs |
| Company name: | EVER GROWTH (VIETNAM) CORPORATION LIMITED |
| 510(K) Number: | K190736 |

# 510(k) SUMMARY

**5.0 Device Description:**

This device, Disposable Powder Free Nitrile Examination Glove, Natural Blue Color, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, is a nitrile non-sterile medical examination glove available in various sizes (from extra-small to extra-large) and packaging configuration. The gloves are non-sterile medical examination gloves, seamless, ambidextrous, five fingered. They are made from proprietary formulations composed of NBR (Nitrile Butadiene Rubber), accelerator, bulking agent, and pigment. In addition, no former release powder or chemical is used in its manufacturing process.

**6.0 Device Indications for use:**

A non-powdered 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. In addition, these gloves were tested respectively for use with chemotherapy drugs and Fentanyl citrate in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by

| No. | Test Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Min.)* |
|---|---|---|
| 1 | Bleomycin Sulfate 15.0 mg/ml | > 240 |
| 2 | Busulfan 6.0 mg/ml | > 240 |
| 3 | Carboplatin 10.0 mg/ml | > 240 |
| 4 | Carmustine (BCNU) 3.3 mg/ml | 59.4 |
| 5 | Chloroquine 50.0 mg/ml | > 240 |
| 6 | Cisplatin 1 mg/ml | > 240 |
| 7 | Cyclophosphamide 20 mg/ml | > 240 |
| 8 | Cyclosporin A 100.0 mg/ml | > 240 |
| 9 | Cytarabine 100.0 mg/ml | > 240 |
| 10 | Dacarbazine (DTIC), 10.0 mg/ml | > 240 |
| 11 | Daunorubicin 5.0 mg/ml | > 240 |
| 12 | Docetaxel 10.0 mg/ml | > 240 |
| 13 | Doxorubicin Hydrochloride 2.0 mg/ml | > 240 |
| 14 | Epirubicin 2.0 mg/ml | > 240 |
| 15 | Etoposide (Toposar), 20.0 mg/ml | > 240 |
| 16 | Fludarabine 25.0 mg/ml | > 240 |
| 17 | Fluorouracil 50.0 mg/ml | > 240 |
| 18 | Gemcitabine 38.0 mg/ml | > 240 |

# 510(k) SUMMARY

| No. | Test Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Min.)* |
|---|---|---|
| 19 | Idaribicin 1.0 mg/ml | > 240 |
| 20 | Ifosfamide 50.0 mg/ml | > 240 |
| 21 | Irinotecan 20.0 mg/ml | > 240 |
| 22 | Mechlorethamine HCl 1.0 mg/ml | > 240 |
| 23 | Melphalan 5.0 mg/ml | > 240 |
| 24 | Methotrexate 25 mg/ml | > 240 |
| 25 | Mitomycin C 0.5 mg/ml | > 240 |
| 26 | Mitoxantrone 2.0 mg/ml | > 240 |
| 27 | Oxaliplatin 2.0 mg/ml | > 240 |
| 28 | Paclitaxel (Taxol) 6.0 mg/ml | > 240 |
| 29 | Paraplatin 10 mg/ml | > 240 |
| 30 | Retrovir 10 mg/ml | > 240 |
| 31 | Rituximab 10 mg/ml | > 240 |
| 32 | Thiotepa 10.0 mg/ml | 118.5 |
| 33 | Topotecan HCl 1.0 mg/ml | > 240 |
| 34 | Trisonex 1.0 mg/ml | > 240 |
| 35 | Velcade (Bortezomib) 1.0 mg/ml | > 240 |
| 36 | Vincristine 1.0 mg/ml | > 240 |
| Fentanyl Citrate Test | | |
| | Fentanyl Citrate Injection 100 mcg/2ml | >240 |

*The maximum testing time is 240 minutes

Please note that the following drug has an extremely low permeation time:

| No. | Test Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Min.) |
|---|---|---|
| 4 | Carmustine (BCNU) 3.3 mg/ml | 59.4 |
| 32 | Thiotepa, 10.0 mg/ml | 118.5 |

# 510(k) SUMMARY

## 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 | Disposable Powder Free Nitrile Examination Glove, Natural Blue Color, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | same except color |
| 510(K) No. | K190736 | K234097 | n/a |
| Product Owner | Ever Growth (Vietnam) Corporation Limited | Ever Growth (Vietnam) Corporation Limited | same |
| Product Code | LZA & LZC | LZA & LZC, OPJ, QDO | same |
| Regulation | 21 CFR 880.6250 | 21 CFR 880.6250 | same |
| Class | I | I | same |
| 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 in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs. | 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 Medical gloves to Permeation by Chemotherapy Drugs. | similar |
| 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 |
| Dimensions-Length | Complies with ASTM D6319-10 ≥ 230 mm | Complies with ASTM D6319-19<br>XS&S ≥ 220 mm;<br>M&L&XL ≥ 230 mm | similar |
| Dimensions - Palm Width | Complies with ASTM D6319-10<br>XS: 70 ± 10 mm;<br>S: 80 ± 10 mm;<br>M: 95 ± 10 mm;<br>L: 110 ± 10 mm;<br>XL: 120 ± 10 mm | Complies with ASTM D6319-19<br>XS: 70 ± 10 mm;<br>S: 80 ± 10 mm;<br>M: 95 ± 10 mm;<br>L: 110 ± 10 mm;<br>XL: 120 ± 10 mm | same |
| Dimensions - Thickness | Complies with ASTM D6319-10<br>Palm ≥0.05 mm;<br>Finger ≥0.05 mm | Complies with ASTM D6319-19<br>Palm ≥0.05 mm;<br>Finger ≥0.05 mm | same |

# 510(k) SUMMARY

<table>
<tr><th>Device Characteristic</th><th>Predicate Device</th><th>Subject Device</th><th>Comparison</th></tr>
<tr><td rowspan="2">Physical Properties</td><td>Complies with ASTM D6319-10<br>Tensile Strength<br>Before aging≥14MPa<br>After aging ≥14MPa</td><td>Complies with ASTM D6319-19<br>Tensile Strength<br>Before aging≥14MPa<br>After aging ≥14MPa</td><td>same</td></tr>
<tr><td>Complies with ASTM D6319-10<br>Elongation:<br>Before Aging: 500% min.<br>After Aging: 400% min.</td><td>Complies with ASTM D6319-19<br>Elongation:<br>Before Aging: 500% min.<br>After Aging: 400% min.</td><td>same</td></tr>
<tr><td>Residual powder</td><td>Complies with ASTM D6319-10<br>< 2mg per glove</td><td>Complies with ASTM D6319-19<br>< 2mg per glove</td><td>same</td></tr>
<tr><td>Freedom from Holes</td><td>In accordance with ASTM D D6319-10 (G-1 with AQL 2.5)</td><td>In accordance with ASTM D6319-19 (G-1 with AQL 2.5)</td><td>same</td></tr>
<tr><td rowspan="3">Biocompatibility</td><td>AAMI/ ANSI/ ISO 10993-5, In vitro cytotoxicity test: Passes</td><td>ISO 10993-5: 2009, In vitro cytotoxicity test: Pass</td><td>same</td></tr>
<tr><td rowspan="2">AAMI/ANSI/ISO 10993-10, Skin sensitization test & Skin Irritation test: Passes</td><td>10993-10:2021, Tests for skin sensitization: Pass</td><td>same</td></tr>
<tr><td>CPSC standards regulated under the FHSA Act set forth in 16 CFR 1500.41,<br>Irritation/Corrosion Test: Pass</td><td>similar</td></tr>
<tr><td>Resistance of Gloves to Permeation by Chemotherapy Drugs</td><td>
<table>
<tr><th>no.</th><th>Test Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time (Min.)</th></tr>
<tr><td>1</td><td>Bleomycin Sulfate 15.0 mg/ml</td><td>> 240</td></tr>
<tr><td>2</td><td>Busulfan 6.0 mg/ml</td><td>> 240</td></tr>
<tr><td>3</td><td>Carboplatin 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>4</td><td>Carmustine (BCNU), 3.3 mg/ml</td><td>59.4</td></tr>
<tr><td>5</td><td>Chloroquine 50.0 mg/ml</td><td>> 240</td></tr>
<tr><td>6</td><td>Cisplatin 1.0 mg/ml</td><td>> 240</td></tr>
<tr><td>7</td><td>Cyclophosphamide 20 mg/ml</td><td>> 240</td></tr>
<tr><td>8</td><td>Cyclosporin A 100.0 mg/ml</td><td>> 240</td></tr>
<tr><td>9</td><td>Cytarabine 100.0 mg/ml</td><td>> 240</td></tr>
<tr><td>10</td><td>Dacarbazine (DTIC), 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>11</td><td>Daunorubicin 5.0 mg/ml</td><td>> 240</td></tr>
<tr><td>12</td><td>Docetaxel 10.0 mg/ml</td><td>> 240</td></tr>
</table>
</td><td>
<table>
<tr><th>no.</th><th>Test Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time (Min.)</th></tr>
<tr><td>1</td><td>Bleomycin Sulfate 15.0 mg/ml</td><td>> 240</td></tr>
<tr><td>2</td><td>Busulfan 6.0 mg/ml</td><td>> 240</td></tr>
<tr><td>3</td><td>Carboplatin 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>4</td><td>Carmustine (BCNU), 3.3 mg/ml</td><td>59.4</td></tr>
<tr><td>5</td><td>Chloroquine 50.0 mg/ml</td><td>> 240</td></tr>
<tr><td>6</td><td>Cisplatin 1.0 mg/ml</td><td>> 240</td></tr>
<tr><td>7</td><td>Cyclophosphamide 20 mg/ml</td><td>> 240</td></tr>
<tr><td>8</td><td>Cyclosporin A 100.0 mg/ml</td><td>> 240</td></tr>
<tr><td>9</td><td>Cytarabine 100.0 mg/ml</td><td>> 240</td></tr>
<tr><td>10</td><td>Dacarbazine (DTIC), 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>11</td><td>Daunorubicin 5.0 mg/ml</td><td>> 240</td></tr>
<tr><td>12</td><td>Docetaxel 10.0 mg/ml</td><td>> 240</td></tr>
</table>
</td><td>similar</td></tr>
</table>

# 510(k) SUMMARY

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 13 | Doxorubicin Hydrochloride, 2.0 mg/ml | > 240 | 13 | Doxorubicin Hydrochloride, 2.0 mg/ml | > 240 | |
| | 14 | Epirubicin 2.0 mg/ml | > 240 | 14 | Epirubicin 2.0 mg/ml | > 240 | |
| | 15 | Etoposide (Toposar), 20.0 mg/ml | > 240 | 15 | Etoposide (Toposar), 20.0 mg/ml | > 240 | |
| | 16 | Fludarabine 25.0 mg/ml | > 240 | 16 | Fludarabine 25.0 mg/ml | > 240 | |
| | 17 | Fluorouracil, 50.0 mg/ml | > 240 | 17 | Fluorouracil, 50.0 mg/ml | > 240 | |
| | 18 | Gemcitabine 38.0 mg/ml | > 240 | 18 | Gemcitabine 38.0 mg/ml | > 240 | |
| | 19 | Idaribicin 1.0 mg/ml | > 240 | 19 | Idaribicin 1.0 mg/ml | > 240 | |
| | 20 | Ifosfamide 50.0 mg/ml | > 240 | 20 | Ifosfamide 50.0 mg/ml | > 240 | |
| | 21 | Irinotecan 20.0 mg/ml | > 240 | 21 | Irinotecan 20.0 mg/ml | > 240 | |
| | 22 | Mechlorethamine HCl 1.0 mg/ml | > 240 | 22 | Mechlorethamine HCl 1.0 mg/ml | > 240 | |
| | 23 | Melphalan 5.0 mg/ml | > 240 | 23 | Melphalan 5.0 mg/ml | > 240 | |
| | 24 | Methotrexate 25 mg/ml | > 240 | 24 | Methotrexate 25 mg/ml | > 240 | |
| | 25 | Mitomycin C 0.5 mg/ml | > 240 | 25 | Mitomycin C 0.5 mg/ml | > 240 | |
| | 26 | Mitoxantrone 2.0 mg/ml | > 240 | 26 | Mitoxantrone 2.0 mg/ml | > 240 | |
| | 27 | Oxaliplatin 2.0 mg/ml | > 240 | 27 | Oxaliplatin 2.0 mg/ml | > 240 | |
| | 28 | Paclitaxel (Taxol), 6.0 mg/ml | > 240 | 28 | Paclitaxel (Taxol), 6.0 mg/ml | > 240 | |
| | 29 | Paraplatin 10 mg/ml | > 240 | 29 | Paraplatin 10 mg/ml | > 240 | |
| | 30 | Retrovir 10 mg/ml | > 240 | 30 | Retrovir 10 mg/ml | > 240 | |
| | 31 | Rituximab 10 mg/ml | > 240 | 31 | Rituximab 10 mg/ml | > 240 | |
| | 32 | Thiotepa, 10.0 mg/ml | 118.5 | 32 | Thiotepa, 10.0 mg/ml | 118.5 | |
| | 33 | Topotecan HCl 1.0 mg/ml | > 240 | 33 | Topotecan HCl 1.0 mg/ml | > 240 | |
| | 34 | Trisonex 1.0 mg/ml | > 240 | 34 | Trisonex 1.0 mg/ml | > 240 | |
| | 35 | Velcade (Bortezomib) 1.0 mg/ml | > 240 | 35 | Velcade (Bortezomib) 1.0 mg/ml | > 240 | |
| | 36 | Vincristine 1.0 mg/ml | > 240 | 36 | Vincristine 1.0 mg/ml | > 240 | |
| | 37 | Fentanyl Citrate Injection 100 mcg/2ml | n/a | 37 | Fentanyl Citrate Injection 100 mcg/2ml | >240 | |

# 510(k) SUMMARY

## 8.0 Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for the Disposable Powder Free Nitrile Examination Glove, Natural Blue Color, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.:

| Test | Test Method | Purpose | Acceptance Criteria | Results |
|---|---|---|---|---|
| Dimension | ASTM D3767 | Determine the geometrical dimension of gloves | Length: XS&S ≥ 220 mm; M&L&XL ≥ 230 mm.<br>Thickness:<br>Palm - 0.05 mm min.<br>Finger - 0.05 mm min.<br>Palm Width:<br>X-small 70 ± 10 mm<br>Small 85 ± 10 mm<br>Medium 95± 10 mm<br>Large 110 ± 10 mm<br>X-Large 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 D412-16 & ASTM D573-04 | 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: 14 MPa, min.<br>After Aging: 14 MPa, min | Pass |
| Elongation (Before aging/After aging) | ASTM D412-16 & ASTM D573-04 | | Before Aging: 500% min.<br>After Aging: 400% min. | Pass |
| Powder Residual | ASTM D6124-06 | Determine the average powder mass found on the gloves | < 2mg per glove | Pass |
| Biocompatibility-cytotoxicity | ISO 10993-5:2009 | determine the cytotoxicity potential of glove | No *in vitro* cytotoxic as described in ISO 10993-5 | Pass |
| Biocompatibility-Skin Sensitization | ISO 10993-10:2021 | determine the potential of glove to promote skin sensitization after repeated applications | No dermal reactions indicative of delayed contact hypersensitivity | Pass |
| Biocompatibility-Skin Irritation | CPSC standards regulated under the FHSA Act set forth in 16 CFR 1500.41, | determine the potential of glove to promote irritation reactions after repeated applications | Not dermal irritation reactions | Pass |

# 510(k) SUMMARY

| Test | Test Method | Purpose | Acceptance Criteria | Results |
|---|---|---|---|---|
| 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 37 chemotherapy drugs and Fentanyl Citrate | 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, Natural 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 device.