August 7, 2023

Better Care Plastic Technology Co., Ltd
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K223713
Trade/Device Name: Powder Free Nitrile Examination Glove (Grey) 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, QDO, OPJ
Dated: July 6, 2023
Received: July 6, 2023

Dear Kathy Liu:

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

# Indications for Use

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

510(k) Number *(if known)*
K223713

Device Name
Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
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.

| Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|
| Arsenic Trioxide (1 mg/ml) | >240 |
| Azacitidine (25 mg/ml) | >240 |
| Bendamustine HCL (5 mg/ml) | >240 |
| Bleomycin sulfate (15 mg/ml) | >240 |
| Bortezomib (1 mg/ml) | >240 |
| Busulfan (6 mg/ml) | >240 |
| Carboplatin (10 mg/ml) | >240 |
| Carfilzomib (2 mg/ml) | >240 |
| Carmustine (3.3 mg/ml) | 13.9 |
| Cetuximab (2 mg/ml) | >240 |
| Cisplatin (1 mg/ml) | >240 |
| Cyclophosphamide (20 mg/ml) | >240 |
| Cytarabine (Cytosine) (100 mg/ml) | >240 |
| Cytovene (10 mg/ml) | >240 |
| Dacarbazine (DTIC) (10 mg/ml) | >240 |
| Daunorubicin HCL (5 mg/ml) | >240 |
| Decitabine (5-Aza-2'-deoxycytidine) (5 mg/ml) | >240 |
| Docetaxel (10 mg/ml) | >240 |
| Doxorubicin Hydrochloride (2 mg/ml) | >240 |
| Epirubicin HCL(Ellence) (2 mg/ml) | >240 |
| Eribulin Mesylate (0.5 mg/ml) | >240 |
| Etoposide (Toposar) (20 mg/ml) | >240 |
| Fludarabine (25 mg/ml) | >240 |
| 5-Fluorouracil (50 mg/ml) | >240 |
| Fulvestrant (50 mg/ml) | >240 |
| Gemcitabine (38 mg/ml) | >240 |
| Idarubicin (1.0 mg/ml) | >240 |
| Ifosfamide (50 mg/ml) | >240 |
| Irinotecan HCL (20 mg/ml) | >240 |
| Mechlorethamine HCL (1 mg/ml) | >240 |
| Melphalan (5 mg/ml) | >240 |
| Methotrexate (25 mg/ml) | >240 |
| Mitomycin-C (0.5 mg/ml) | >240 |
| Mitoxantrone (2 mg/ml) | >240 |
| Oxaliplatin (2 mg/ml) | >240 |
| Paclitaxel (6 mg/ml) | >240 |
| Paraplatin (10 mg/ml) | >240 |
| Pemetrexed (25 mg/ml) | >240 |

| | |
|---|---|
| Pertuzumab (30 mg/ml) | >240 |
| Raltitrexed monohydrate (0.5 mg/ml) | >240 |
| Retrovir (10 mg/ml) | >240 |
| Rituximab (10 mg/ml) | >240 |
| Temsirolimus (25 mg/ml) | >240 |
| Thiotepa (10 mg/ml) | 44.4 |
| Topotecan HCL (1 mg/ml) | >240 |
| Trastuzumab (21 mg/ml) | >240 |
| Trisenox (1 mg/ml) | >240 |
| Vinblastine (1 mg/ml) | >240 |
| Vincrinstine Sulfate (1 mg/ml) | >240 |
| Vinorelbine (10 mg/ml) | >240 |
| Zoledronic Acid (0.8 mg/ml) | >240 |

| Fentanyl Citrate and Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|
| Fentanyl Citrate Injection (100mcg/2mL) | >240 |
| Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution | >240 |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 13.9 minutes, Thio Tepa: 44.4 minutes
Warning: Do not use with Carmustine and Thio Tepa.

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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# Better Care Plastic Technology Co., Ltd

Fuqian Xi Road, West district of Shenze, Industrial Base,
Shenze County, Hebei, 050000, China

## 510(K)
## SUMMARY

The assigned 510(K) numbers: K223713
Date Prepared: August 2, 2023

### 1. Owner's Identification:

Mrs. Zhu Chunyan
Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze, Industrial Base, Shenze County, Hebei, 050000,
China Tel:86-311-66179668
Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Avenue, Chino, CA 91710, USA Tel:909-590-1611
Email: fdareg@hongray.com.cn or kathyliu@hongrayusa.com

### 2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name: Exam Gloves
Classification Name: Non-Powdered Patient Examination Glove Specialty
Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
OPJ Classification Panel: General
Hospital Device Class: Class I

### 3. Predicate Device Information:

Primary Predicate Device:
Better Care Plastic Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K221269)

Reference device:
O & M Halyard, Inc.
Halyard Sterling* Nitrile Powder-Free Exam Gloves, Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves (K191230)
This reference device is being used to support inclusion of additional chemotherapy drugs that were not tested in the predicate.

### 4. Device Description:

Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2019). The gloves are single use, disposable, and provided non-sterile.

### 5. Indications for Use:

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.

The following chemicals have been tested with these gloves:

Table 1

| Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|
| Arsenic Trioxide (1 mg/ml) | >240 |
| Azacitidine (25 mg/ml) | >240 |
| Bendamustine HCL (5 mg/ml) | >240 |
| Bleomycin sulfate (15 mg/ml) | >240 |
| Bortezomib (1 mg/ml) | >240 |
| Busulfan (6 mg/ml) | >240 |
| Carboplatin (10 mg/ml) | >240 |
| Carfilzomib (2 mg/ml) | >240 |
| Carmustine (3.3 mg/ml) | 13.9 |
| Cetuximab (2 mg/ml) | >240 |
| Cisplatin (1 mg/ml) | >240 |
| Cyclophosphamide (20 mg/ml) | >240 |
| Cytarabine (Cytosine) (100 mg/ml) | >240 |
| Cytovene (10 mg/ml) | >240 |
| Dacarbazine (DTIC) (10 mg/ml) | >240 |
| Daunorubicin HCL (5 mg/ml) | >240 |
| Decitabine (5-Aza-2'-deoxycytidine) (5 mg/ml) | >240 |
| Docetaxel (10 mg/ml) | >240 |
| Doxorubicin Hydrochloride (2 mg/ml) | >240 |
| Epirubicin HCL(Ellence) (2 mg/ml) | >240 |
| Eribulin Mesylate (0.5 mg/ml) | >240 |
| Etoposide (Toposar) (20 mg/ml) | >240 |
| Fludarabine (25 mg/ml) | >240 |
| 5-Fluorouracil (50 mg/ml) | >240 |
| Fulvestrant (50 mg/ml) | >240 |
| Gemcitabine (38 mg/ml) | >240 |
| Idarubicin (1.0 mg/ml) | >240 |
| Ifosfamide (50 mg/ml) | >240 |
| Irinotecan HCL (20 mg/ml) | >240 |
| Mechlorethamine HCL (1 mg/ml) | >240 |
| Melphalan (5 mg/ml) | >240 |
| Methotrexate (25 mg/ml) | >240 |
| Mitomycin-C (0.5 mg/ml) | >240 |

| | |
|---|---|
| Mitoxantrone (2 mg/ml) | >240 |
| Oxaliplatin (2 mg/ml) | >240 |
| Paclitaxel (6 mg/ml) | >240 |
| Paraplatin (10 mg/ml) | >240 |
| Pemetrexed (25 mg/ml) | >240 |
| Pertuzumab (30 mg/ml) | >240 |
| Raltitrexed monohydrate (0.5 mg/ml) | >240 |
| Retrovir (10 mg/ml) | >240 |
| Rituximab (10 mg/ml) | >240 |
| Temsirolimus (25 mg/ml) | >240 |
| Thiotepa (10 mg/ml) | 44.4 |
| Topotecan HCL (1 mg/ml) | >240 |
| Trastuzumab (21 mg/ml) | >240 |
| Trisenox (1 mg/ml) | >240 |
| Vinblastine (1 mg/ml) | >240 |
| Vincrinstine Sulfate (1 mg/ml) | >240 |
| Vinorelbine (10 mg/ml) | >240 |
| Zoledronic Acid (0.8 mg/ml) | >240 |

| Fentanyl Citrate and Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|
| Fentanyl Citrate Injection (100mcg/2mL) | >240 |
| Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution | >240 |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 13.9 minutes, Thio Tepa: 44.4 minutes
Warning: Do not use with Carmustine and Thio Tepa.

**6. Comparison of Subject Device and Predicate Device:**

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs & Fentanyl Citrate of the proposed and predicate devices.
General Comparison Table:

| | Subject Device K223713 | Predicate Device K221269 | Reference Device K191230 | Comparison |
|---|---|---|---|---|
| Trade Name | Powder Free Nitrile Examination Glove (Grey) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | Powder Free Nitrile Examination Glove (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | Halyard Sterling* Nitrile Powder-Free Exam Gloves, Halyard Sterling SG* Nitrile Sensi-Guard Powder-Free Exam Gloves | Similar |
| Product Code | LZA, LZC, QDO, OPJ | LZA, LZC,QDO | LZC | Different * |
| Regulation Number | 21 CFR 880.6250 | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |

| Class | I | I | I | Same |
|---|---|---|---|---|
| Indications for Use | The device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs and Fentanyl listed on the label. | The device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs and Fentanyl listed on the label. | The device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs listed on the label. | Same as K221269* |
| Material | Nitrile | Nitrile | Nitrile | Same |
| Powder or Powder Free | Powder Free | Powder Free | Powder Free | Same |
| Color | Grey | Blue | Grey | Different from K221269** Same as K191230 |
| Single use | Single use | Single use | Single use | Same |
| Dermal Irritation ISO 10993-10 | Based on the criteria, the test article extracts were considered negligible irritants. | Under the conditions of the study, not an irritant | Based on the criteria and conditions of the study, the test article was considered nonirritating | Same |
| Dermal Sensitization ISO 10993-10 | Based on the criteria and conditions of the study, the test article is classified as a non-sensitizer | Under the conditions of the study, not a sensitizer | Based on the criteria and conditions of the study, the test article showed no evidence of causing delayed dermal contact sensitization | Same |
| Cytotoxicity Test ISO 10993-5 | / | Under the conditions of this study, the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systematic toxicity testing. | / | Different from K221269 Same as K191230 |
| Acute Systemic Toxicity ISO 10993-11 | Based on the criteria, the test article meets the requirements | Under the conditions of this study, there was no evidence of systemic toxicity. | No mortality of evidence of systemic toxicity from the extracts | Same |
| Chemotherapy Drugs and Fentanyl Citrate Claim | See below comparison table | See below comparison table | See below comparison table | / |

** QDO and OPJ, both designated for Medical Gloves with Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs, the subject device added the product code OPJ as per requirements but does not raise questions of safety and effectiveness.*
*** The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table:

| Technological Characteristics | Subject Device K223713 | Predicate Device K221269 | Reference Device K191230 | Comparison |
|---|---|---|---|---|
| Physical Dimension | | | | |
| Length | Minimum 230mm | Minimum 230mm | Minimum 230mm | Same |
| Palm Width (size) (mm) | | | | |
| XS | 70±10 | 70±10 | 70±10 | Same |
| S | 80±10 | 80±10 | 80±10 | Same |
| M | 95±10 | 95±10 | 95±10 | Same |
| L | 110±10 | 110±10 | 110±10 | Same |
| XL | 120±10 | 120±10 | 120±10 | Same |
| Thickness(mm) | | | | |
| Finger | Minimum 0.05 | Minimum 0.05 | Minimum 0.05 | Same |
| Palm | Minimum 0.05 | Minimum 0.05 | Minimum 0.05 | Same |
| Physical Property | | | | |
| Tensile Strength, Before Aging | 14MPa, min | 14MPa, min | 14MPa, min | Same |
| Ultimate Elongation, Before Aging | 500%, min | 500%, min | 500%, min | Same |
| Tensile Strength, After Accelerated Aging | 14MPa, min | 14MPa, min | 14MPa, min | Same |
| Ultimate Elongation, After Accelerated Aging | 400%, min | 400%, min | 400%, min | Same |
| Watertight (1000ml) | G-I, AQL2.5 | G-I, AQL2.5 | G-I, AQL2.5 | Same |
| Powder-Content | ≤ 2 mg per glove | ≤ 2 mg per glove | ≤ 2 mg per glove | Same |

Chemotherapy Permeation and Fentanyl Citrate Comparison Claim:

| Tested Chemotherapy Drug and Concentration | Minimum Breakthrough Detection Time (Minutes) | | | Comparison With K191230 |
|---|---|---|---|---|
| | Subject Device K223713 | Reference Device K191230 | Predicate Device K221269 | |
| Arsenic Trioxide (1 mg/ml) | >240 | >240 | / | Same |
| Azacitidine (25 mg/ml) | >240 | >240 | / | Same |
| Bendamustine HCL (5 mg/ml) | >240 | >240 | / | Same |

| | | | | |
|---|---|---|---|---|
| Bleomycin sulfate (15 mg/ml) | >240 | >240 | >240 | Same |
| Bortezomib (1 mg/ml) | >240 | >240 | / | Same |
| Busulfan (6 mg/ml) | >240 | >240 | >240 | Same |
| Carboplatin (10 mg/ml) | >240 | >240 | >240 | Same |
| Carfilzomib (2 mg/ml) | >240 | >240 | / | Same |
| Carmustine (3.3 mg/ml) | 13.9 | 14.8 | 11.1 | Similar |
| Cetuximab (2 mg/ml) | >240 | >240 | / | Same |
| Cisplatin (1 mg/ml) | >240 | >240 | >240 | Same |
| Cyclophosphamide (20 mg/ml) | >240 | >240 | >240 | Same |
| Cytarabine (Cytosine) (100 mg/ml) | >240 | >240 | >240 | Same |
| Cytovene (10 mg/ml) | >240 | >240 | / | Same |
| Dacarbazine (DTIC) (10 mg/ml) | >240 | >240 | >240 | Same |
| Daunorubicin HCL (5 mg/ml) | >240 | >240 | >240 | Same |
| Decitabine (5-Aza-2'-deoxycytidine) (5 mg/ml) | >240 | >240 | / | Same |
| Docetaxel (10 mg/ml) | >240 | >240 | >240 | Same |
| Doxorubicin Hydrochloride (2 mg/ml) | >240 | >240 | >240 | Same |
| Epirubicin HCL(Ellence) (2 mg/ml) | >240 | >240 | >240 | Same |
| Eribulin Mesylate (0.5 mg/ml) | >240 | >240 | / | Same |
| Etoposide (Toposar) (20 mg/ml) | >240 | >240 | >240 | Same |
| Fludarabine (25 mg/ml) | >240 | >240 | >240 | Same |
| 5-Fluorouracil (50 mg/ml) | >240 | >240 | >240 | Same |
| Fulvestrant (50 mg/ml) | >240 | >240 | / | Same |
| Gemcitabine (38 mg/ml) | >240 | >240 | >240 | Same |
| Idarubicin (1.0 mg/ml) | >240 | >240 | | Same |
| Ifosfamide (50 mg/ml) | >240 | >240 | >240 | Same |
| Irinotecan HCL (20 mg/ml) | >240 | >240 | >240 | Same |
| Mechlorethamine HCL (1 mg/ml) | >240 | >240 | >240 | Same |
| Melphalan (5 mg/ml) | >240 | >240 | >240 | Same |
| Methotrexate (25 mg/ml) | >240 | >240 | >240 | Same |
| Mitomycin-C (0.5 mg/ml) | >240 | >240 | >240 | Same |
| Mitoxantrone (2 mg/ml) | >240 | >240 | >240 | Same |
| Oxaliplatin (2 mg/ml) | >240 | >240 | >240 | Same |
| Paclitaxel (6 mg/ml) | >240 | >240 | >240 | Same |
| Paraplatin (10 mg/ml) | >240 | >240 | >240 | Same |
| Pemetrexed (25 mg/ml) | >240 | >240 | / | Same |
| Pertuzumab (30 mg/ml) | >240 | >240 | / | Same |
| Raltitrexed monohydrate (0.5 mg/ml) | >240 | >240 | / | Same |
| Retrovir (10 mg/ml) | >240 | >240 | >240 | Same |
| Rituximab (10 mg/ml) | >240 | >240 | >240 | Same |
| Temsirolimus (25 mg/ml) | >240 | >240 | / | Same |

| | | | | |
|---|---|---|---|---|
| Thiotepa (10 mg/ml) | 44.4 | 23.9 | 21.6 | Similar |
| Topotecan HCL (1 mg/ml) | >240 | >240 | >240 | Same |
| Trastuzumab (21 mg/ml) | >240 | >240 | / | Same |
| Trisenox (1 mg/ml) | >240 | >240 | >240 | Same |
| Vinblastine (1 mg/ml) | >240 | >240 | / | Same |
| Vincrinstine Sulfate (1 mg/ml) | >240 | >240 | >240 | Same |
| Vinorelbine (10 mg/ml) | >240 | >240 | / | Same |
| Zoledronic Acid (0.8 mg/ml) | >240 | >240 | / | Same |
| Tested Fentanyl Citrate and Concentration | | | | |
| Fentanyl Citrate Injection (100mcg/2mL) | >240 | / | >240 | Different* |
| Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix 50/50 Solution | >240 | / | / | Different* |

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this different does not raise questions of safety and effectiveness.*

**7. Summary of Non-Clinical Performance Data**

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

| Methodology | Test Performed | Acceptance Criteria | Results |
|---|---|---|---|
| ASTM D6319- 19 | Physical Dimensions Length | Minimum 220mm for size XS and S, 230mm for size M, L, XL | Pass |
| ASTM D6319- 19 | Physical Dimensions Palm Width | XS: 70±10mm<br>S: 80±10mm<br>M: 95±10mm<br>L:110±10mm<br>XL：120±10mm | Pass |
| ASTM D6319- 19 | Physical Dimensions Thickness | Finger: 0.05mm (min)<br>Palm: 0.05mm (min) | Pass |
| ASTM D6319- 19<br>ASTM D412-16 (2021) | Physical Properties | Tensile Strength (Min14 Mpa) and Elongation (Before Aging 500% and after aging 400%) Min | Pass |
| ASTM D6319- 19<br>ASTM D5151-19 | Water leak test | G-I, AQL 2.5 (ISO 2859-1) | Pass |
| ASTM D6319- 19<br>ASTM D6124-06 (2017) | Powder Residue | Max 2mg/glove | Pass |
| ASTM D6978-05 (2019) | Permeation by Chemotherapy Drugs | Refer the above table 1 | Pass |
| ISO 10993-10:2010 | Irritation and Skin Sensitization | No Skin sensitization and Skin irritation | Is non-sensitization and Non-irritation |
| ISO 10993-5:2009 | Cytotoxicity | No Cytotoxicity reactivity | showed potential toxicity to L929 cells. |
| ISO 10993-11:2017 | Acute systemic toxicity study | Subject showed no adverse biological reaction | no evidence of acute systemic toxicity. |

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

**8. Summary of Clinical Testing:** Not provided for the subject device.

**9. Conclusion:**
The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.