March 28, 2024

WRP Asia Pacific Sdn. Bhd.
% Michael Scaglione
U.S. Agent
WRP USA Inc
3700 Massillon Road, Suite 340
Uniontown, Ohio 44685

Re: K232079
Trade/Device Name: Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green); Natural Rubber Latex (Strip&Coat)/(Strip&Pack) Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-powdered surgeon's glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, OPJ, QDO
Dated: March 5, 2024
Received: March 26, 2024

Dear Michael Scaglione:

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,

Allan Guan -S

For 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

# Indications for Use

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

510(k) Number *(if known)*
K232079

Device Name
Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green); Natural Rubber Latex (Strip&Coat)/(Strip&Pack) Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl

Indications for Use *(Describe)*
A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

NATURAL RUBBER LATEX SURGICAL GLOVE, POWDER FREE, STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL (GREEN):

| Chemotherapy Drug | Concentration | Average Breakthrough Detection Time (Minutes) |
|---|---|---|
| Cisplatin | (1.0 mg/ml) | > 240 |
| Cyclophosphamide (Cytoxan) | (20.0 mg/ml) | > 240 |
| Dacarbazine | (10.0 mg/ml) | > 240 |
| Doxorubicin Hydrochloride | (2.0 mg/ml) | > 240 |
| Etoposide | (20.0 mg/ml) | > 240 |
| Fluorouracil | (50.0 mg/ml) | > 240 |
| Ifosfamide | (50.0 mg/ml) | > 240 |
| Methotrexate | (25.0 mg/ml) | > 240 |
| Mitomycin C | (0.5 mg/ml) | > 240 |
| Mitoxantrone | (2.0 mg/ml) | > 240 |
| Paclitaxel | (6.0 mg/ml) | > 240 |
| Vincristine Sulfate | (1.0 mg/ml) | > 240 |
| *Thiotepa | (10.0 mg/ml) | 14.7 |
| *Carmustine (BCNU) | (3.3 mg/ml) | 11.9 |

| Opioid Drug | Breakthrough Detection Time in Minutes |
|---|---|
| Fentanyl Citrate 100 mcg/2mL | No breakthrough up to 240 minutes |

*WARNING: Testing showed an average breakthrough time of 11.9 minutes for Carmustine and an average breakthrough time of 14.7 minutes for Thiotepa. Do not use with Carmustine and Thiotepa.

NATURAL RUBBER LATEX (STRIP&COAT)/(STRIP&PACK) SURGICAL GLOVE, POWDER FREE, STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL:

| Chemotherapy Drug | Concentration | Average Breakthrough Detection Time (Minutes) |
|---|---|---|
| Cisplatin | (1.0 mg/ml) | > 240 |
| Cyclophosphamide (Cytoxan) | (20.0 mg/ml) | > 240 |
| Dacarbazine | (10.0 mg/ml) | > 240 |
| Doxorubicin Hydrochloride | (2.0 mg/ml) | > 240 |
| Etoposide | (20.0 mg/ml) | > 240 |

| | |
|---|---|
| Fluorouracil (50.0 mg/ml) | > 240 |
| Ifosfamide (50.0 mg/ml) | > 240 |
| Methotrexate (25.0 mg/ml) | > 240 |
| Mitomycin C (0.5 mg/ml) | > 240 |
| Mitoxantrone (2.0 mg/ml) | > 240 |
| Paclitaxel (6.0 mg/ml) | > 240 |
| Vincristine Sulfate (1.0 mg/ml) | > 240 |
| *Thiotepa (10.0 mg/ml) | 13.8 |
| *Carmustine (BCNU) (3.3 mg/ml) | 5.7 |

| Opioid Drug | Breakthrough Detection Time in Minutes |
|---|---|
| Fentanyl Citrate 100 mcg/2mL | No breakthrough up to 240 minutes |

*WARNING: Testing showed an average breakthrough time of 5.7 minutes for Carmustine and an average breakthrough time of 13.8 minutes for Thiotepa. Do not use with Carmustine and Thiotepa.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) SUMMARY, K232079

## 1.0 Submitter:

| | | |
|---|---|---|
| Name | : | Muhammad Ameer Arief bin Mohd Mujab |
| Address | : | WRP Asia Pacific Sdn. Bhd.<br>Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA |
| Phone No. | : | +60 3 8706 1486 |
| Fax No. | : | +60 3 8706 1557 |
| Date of Summary Prepared | : | 28th March 2024 |

## 2.0 Identification of the Subject Device:

| | | |
|---|---|---|
| Trade Name | : | Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green); Natural Rubber Latex (Strip&Coat)/(Strip&Pack) Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl |
| Common Name | : | Surgical Gloves |
| Classification Name | : | Non-powdered surgeon's glove |
| Device Classification | : | I |
| Regulation Number | : | 21 CFR 878.4460 |
| Product Code | : | KGO, LZC, OPJ, QDO |

## 3.0 Predicate Device:

| | Predicate |
|---|---|
| **Manufacturer** | WRP Asia Pacific Sdn. Bhd. |
| **Device name** | Powder-Free Polymer Coated Latex Surgical Gloves, Sterile with Protein Labelling Claim (50 Micrograms or Less) |
| **510(k) Number** | K020019 |
| **Regulatory Class** | I |
| **Product Code** | KGO |

**4.0 Description of The Device:**

This is a disposable natural rubber surgical glove that is tested for use with chemotherapy drugs and fentanyl resistance. The glove is supplied in the following sizes: 5½, 6, 6½, 7, 7½, 8, 8½ and 9.

**5.0 Indication for use:**

A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

**5.1 Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green)**

| Chemotherapy Drug | Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|---|
| *Carmustine (BCNU) | 3.3 mg/ml | 11.9 |
| Cisplatin | 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | 20.0 mg/ml | >240 |
| Dacarbazine | 10.0 mg/ml | > 240 |
| Doxorubicin Hydrochloride | 2.0 mg/ml | > 240 |
| Etoposide | 20.0 mg/ml | > 240 |
| Fluorouracil | 50.0 mg/ml | > 240 |
| Ifosfamide | 50.0 mg/ml | > 240 |
| Methotrexate | 25.0 mg/ml | > 240 |
| Mitomycin C | 0.5 mg/ml | > 240 |
| Mitoxantrone | 2.0 mg/ml | > 240 |
| Paclitaxel | 6.0 mg/ml | > 240 |
| *Thiotepa | 10.0 mg/ml | 14.7 |
| Vincristine Sulfate | 1.0 mg/ml | > 240 |

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 11.9 minutes and Thiotepa: 14.7. Do not use with Carmustine and Thiotepa.

| Opioid Drug | Concentration | Breakthrough Detection Time in Minutes |
|---|---|---|
| Fentanyl Citrate Injection | 100mcg/2mL | No breakthrough up to 240 minutes |

**5.2 Natural Rubber Latex Surgical Glove (Strip&Coat)/(Strip&Pack), Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl**

| Chemotherapy Drug | Concentration | Minimum Breakthrough Detection Time (Minutes) |
|---|---|---|
| *Carmustine (BCNU) | 3.3 mg/ml | 5.7 |
| Cisplatin | 1.0 mg/ml | >240 |
| Cyclophosphamide (Cytoxan) | 20.0 mg/ml | >240 |
| Dacarbazine | 10.0 mg/ml | > 240 |
| Doxorubicin Hydrochloride | 2.0 mg/ml | > 240 |
| Etoposide | 20.0 mg/ml | > 240 |
| Fluorouracil | 50.0 mg/ml | > 240 |
| Ifosfamide | 50.0 mg/ml | > 240 |
| Methotrexate | 25.0 mg/ml | > 240 |
| Mitomycin C | 0.5 mg/ml | > 240 |
| Mitoxantrone | 2.0 mg/ml | > 240 |
| Paclitaxel | 6.0 mg/ml | > 240 |
| *Thiotepa | 10.0 mg/ml | 13.8 |
| Vincristine Sulfate | 1.0 mg/ml | > 240 |

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 5.7 minutes and Thiotepa: 13.8. Do not use with Carmustine and Thiotepa.

| Opiod Drug | Concentration | Breakthrough Detection Time in Minutes |
|---|---|---|
| Fentanyl Citrate Injection | 100mcg/2mL | No breakthrough up to 240 minutes |

# 510(k) SUMMARY, K232079

**6.0 Summary of the Technological Characteristics of the Device:** *See table*

**Table 1**

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | CURRENT | |
| **510(k) Number** | - | **K020019** | **K232079** | - |
| **Manufacturer(s)** | - | WRP Asia Pacific Sdn. Bhd. | WRP Asia Pacific Sdn. Bhd. | Same |
| **Material** | ASTM D3577 | Natural Rubber Latex | Natural Rubber Latex | Same |
| **Color** | - | Natural White | Green and Natural | Different |
| **Texture** | - | Micro-roughened surface | Micro-roughened surface | Same |
| **Physical Properties**<br><br>**Before Aging**<br>**Tensile Strength:**<br>**Ultimate Elongation:**<br>**Stress at 500% Elongation:** | ASTM D3577 | Meets<br><br>Min. 24MPa<br>Min. 750%<br><br>Max. 5.5MPa | Meets | Same |
| **After Aging**<br>**Tensile Strength:**<br>**Ultimate Elongation:**<br>**Stress at 500% Elongation:** | | Meets<br><br>Min. 18MPa<br>Min. 560%<br><br>N/A | Meets | Same |
| **Thickness:**<br><br>**- Finger**<br>**- Palm**<br>**- Cuff** | ASTM D3577 | Meets<br><br>Min. 0.10 mm<br>Min. 0.10 mm<br>Min. 0.10 mm | Meets<br><br>Min. 0.10 mm<br>Min. 0.10 mm<br>Min. 0.10 mm | Same |
| **Dimension, Length** | ASTM D3577 | Meets<br><br>5½: Min. 245mm<br>6.0: Min. 265 mm<br>6½: Min. 265 mm<br>7.0: Min. 265 mm<br>7½: Min. 265 mm<br>8.0: Min. 265 mm<br>8½: Min. 265 mm<br>9.0: Min. 265 mm | Meets<br><br>5½: Min. 245mm<br>6.0: Min. 265 mm<br>6½: Min. 265 mm<br>7.0: Min. 265 mm<br>7½: Min. 265 mm<br>8.0: Min. 265 mm<br>8½: Min. 265 mm<br>9.0: Min. 265 mm | Same |

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | CURRENT | |
| **510(k) Number** | - | **K020019** | **K232079** | - |
| **Dimension, Width** | ASTM D3577 | Meets<br><br>5½: 70 ± 6 mm<br>6.0: 76 ± 6 mm<br>6½: 83 ± 6 mm<br>7.0: 89 ± 6 mm<br>7½: 95 ± 6 mm<br>8.0: 102 ± 6 mm<br>8½: 108 ± 6 mm<br>9.0: 114 ± 6 mm | Meets<br><br>5½: 70 ± 6 mm<br>6.0: 76 ± 6 mm<br>6½: 83 ± 6 mm<br>7.0: 89 ± 6 mm<br>7½: 95 ± 6 mm<br>8.0: 102 ± 6 mm<br>8½: 108 ± 6 mm<br>9.0: 114 ± 6 mm | Same |
| **Powder Free** | ASTM D6124 | Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577 | Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577 | Same |
| **Biocompatibility** | Primary Skin Irritation – ISO 10993-10 | Passes (Not a primary skin irritant) | Passes (Not a primary skin irritant) | Same |
| | Dermal Sensitization- ISO 10993-10 | Passes (Not a contact sensitizer) | Passes (Not a contact sensitizer) | Same |
| | Acute Systemic Toxicity, ISO 10993-11 | N/A | It is concluded that the devices did not induce any acute systemic toxicity | Different |

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | CURRENT | |
| **510(k) Number** | - | **K020019** | **K232079** | - |
| | Material Mediated Pyrogenicity, ISO 10993-11 | N/A | It is concluded that the devices are non-pyrogenic | Different |
| | Cytotoxicity-Direct Contact, ISO 10993-5 | N/A | Non-cytotoxic for S&C/S&P gloves | Different |
| | Cytotoxicity-MEM Elution, ISO 10993-5 | N/A | Under the conditions of this study, the test article extract showed potential toxicity to L929 cells for Green gloves | Different |
| **Watertight (1000ml)** | ASTM D5151 | Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level I, AQL 0.65 | Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level I, AQL 0.65 | Same |
| **Intended use / Indications for Use** | - | A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient. | A powder-free sterile surgeon's glove is a disposable device made of natural rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient.<br><br>These gloves were tested for use with | Different |

# 510(k) SUMMARY, K232079

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | CURRENT | |
| **510(k) Number** | - | **K020019** | **K232079** | - |
| | | | Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. | |
| **Size** | Medical Glove Guidance Manual - Labeling | 5½<br>6.0<br>6½<br>7.0<br>7½<br>8.0<br>8½<br>9.0 | 5½<br>6.0<br>6½<br>7.0<br>7½<br>8.0<br>8½<br>9.0 | Same |
| **Single Use** | Medical Glove Guidance Manual - Labeling | Single use | Single use | Same |
| **Sterility Status** | Medical Glove Guidance Manual - Labeling | Sterile | Sterile | Same |
| **Sterility Method** | ISO 11137-1<br>ISO 11137-2 | Gamma Radiation | Gamma Radiation | Same |
| **Chemotherapy Drug Permeation Test** | ASTM D6978-05 | | | |
| 1. Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green) | | | | |
| * Carmustine (BCNU) (3.3 mg/ml) | | N/A | 11.9 | Different |
| Cisplatin (1.0 mg/ml) | | N/A | >240 | Different |
| Cyclophosphamide (Cytoxan) (20.0 mg/ml) | | N/A | >240 | Different |

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE | | COMPARISON ANALYSIS |
|---|---|---|---|---|
| | | PREDICATE | CURRENT | |
| **510(k) Number** | - | **K020019** | **K232079** | - |
| Dacarbazine (10.0 mg/ml) | | N/A | > 240 | Different |
| Doxorubicin Hydrochloride (2.0 mg/ml) | | N/A | > 240 | Different |
| Etoposide (20.0 mg/ml) | | N/A | > 240 | Different |
| Fluorouracil (50.0 mg/ml) | | N/A | > 240 | Different |
| Ifosfamide (50.0 mg/ml) | | N/A | > 240 | Different |
| Methotrexate (25.0 mg/ml) | | N/A | > 240 | Different |
| Mitomycin C (0.5 mg/ml) | | N/A | > 240 | Different |
| Mitoxantrone (2.0 mg/ml) | | N/A | > 240 | Different |
| Paclitaxel (6.0 mg/ml) | | N/A | > 240 | Different |
| * ThioTepa (10.0 mg/ml) | | N/A | 14.7 | Different |
| Vincristine Sulfate (1.0 mg/ml) | | N/A | > 240 | Different |
| Warning Statement | | N/A | *WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 11.9 minutes and Thiotepa: 14.7 minutes. Do not use with Carmustine and Thiotepa. | Different |
| **Fentanyl Citrate (100 mcg/2mL)** | ASTM D6978-05 | N/A | > 240 | Different |
| 2. Natural Rubber Latex Surgical Glove (Strip&Coat)/(Strip&Pack), Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl | | | | |
| * Carmustine (BCNU) (3.3 mg/ml) | | N/A | 5.7 | Different |
| Cisplatin (1.0 mg/ml) | | N/A | >240 | Different |

# 510(k) SUMMARY, K232079

| Characteristics | | PREDICATE | CURRENT | Comparison |
|---|---|---|---|---|
| **510(k) Number** | - | **K020019** | **K232079** | - |
| Cyclophosphamide (Cytoxan) (20.0 mg/ml) | | N/A | >240 | Different |
| Dacarbazine (10.0 mg/ml) | | N/A | > 240 | Different |
| Doxorubicin Hydrochloride (2.0 mg/ml) | | N/A | > 240 | Different |
| Etoposide (20.0 mg/ml) | | N/A | > 240 | Different |
| Fluorouracil (50.0 mg/ml) | | N/A | > 240 | Different |
| Ifosfamide (50.0 mg/ml) | | N/A | > 240 | Different |
| Methotrexate (25.0 mg/ml) | | N/A | > 240 | Different |
| Mitomycin C (0.5 mg/ml) | | N/A | > 240 | Different |
| Mitoxantrone (2.0 mg/ml) | | N/A | > 240 | Different |
| Paclitaxel (6.0 mg/ml) | | N/A | > 240 | Different |
| * ThioTepa (10.0 mg/ml) | | N/A | 13.8 | Different |
| Vincristine Sulfate (1.0 mg/ml) | | N/A | > 240 | Different |
| Warning Statement | | N/A | *WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 5.7 minutes and Thiotepa: 13.8 minutes. Do not use with Carmustine and Thiotepa. | Different |
| **Fentanyl Citrate (100 mcg/2mL)** | ASTM D6978-05 | N/A | > 240 | Different |

# 510(k) SUMMARY

## 7.0 Summary of Non-Clinical Testing

| Test Method | Standard | Purpose of Testing | Acceptance Criteria | | | Results | |
|---|---|---|---|---|---|---|---|
| Physical Properties | ASTM D412 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers - Tension) | To evaluate the tensile (tension) properties of glove | | Before Aging | After Aging | Before Aging | After Aging |
| | | | **Tensile strength** | Min. 24MPa | Min. 18MPa | Pass | Pass |
| | | | **Ultimate elongation** | Min. 750% | Min. 560% | Pass | Pass |
| | | | **Stress at 500% Elongation** | Max. 5.5MPa | N/A | Pass | N/A |
| Dimension | ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions) | To measure the length, width and thickness of glove | **Length:** Each size satisfies ASTM requirement | | | Pass | |
| | | | **Width:** Each size satisfies ASTM requirement | | | Pass | |
| Dimension | ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions) | To measure the length, width and thickness of glove | **Thickness** | Finger - Min. 0.10 mm | | Pass | |
| | | | | Palm - Min. 0.10 mm | | Pass | |
| | | | | Cuff - Min. 0.10 mm | | Pass | |
| Watertight | ASTM D5151 (Standard Test Method for Detection of Holes in Medical Gloves) | To measure glove integrity | Freedom from holes at AQL 0.65 | | | Pass | |
| Residual Powder | ASTM D6124 (Standard Test Method for Residual Powder on Medical Gloves) | To determine the amount of residual powder and non-powder solids found on gloves | Have a powder residue limit of 2.0 mg per glove | | | Pass | |
| Protein Content | ASTM D5712 (Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method) | To determine the amount of extractable protein from the glove | ≤ 200 µg/dm2 | | | Pass | |

# 510(k) SUMMARY

| Test Method | Standard | Purpose of Testing | Result Summary |
|---|---|---|---|
| Biocompatibility | Primary Skin Irritation – ISO 10993-10 | To assess the potential of glove to produce dermal irritation | Not a primary skin irritation |
| Biocompatibility | Dermal Sensitization- ISO 10993-10 | To assess the potential of glove to cause a delayed hypersensitivity | Not a contact sensitizer |
| | | (Type IV) immunological response | |
| Biocompatibility | Acute Systemic Toxicity, ISO 10993-11 | To determine the acute systemic toxicity potential of glove | No biological reactivity shown |
| Biocompatibility | Material Mediated Pyrogenicity, ISO 10993-11 | To determine any pyrogenic response induced by the glove | No increase of temperature |
| Biocompatibility | Cytotoxicity- Direct Contact, ISO 10993-5 | To determine the cytotoxicity potential of glove | Non-cytotoxic for S&C/S&P gloves |
| Biocompatibility | Cytotoxicity- MEM Elution, ISO 10993-5 | To determine the cytotoxicity potential of glove | Under the conditions of this study, the test article extract showed potential toxicity to L929 cells for Natural Rubber Latex Green |
| Bacterial endotoxin | Limulus Amoebocyte Lysate (LAL) test | To determine the amount of endotoxin on the glove | ≤20 EU/pair of gloves |

**8.0 Summary of Clinical Testing:**

No clinical study is included in this submission.

**9.0 Conclusion**

The conclusions drawn from the non-clinical tests demonstrate that the subject devices Natural Rubber Latex Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl (Green) and Natural Rubber Latex (Strip&Coat)/(Strip&Pack) Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl are as safe, effective, and perform as well as or better than the legally marketed predicate device K020019.