



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

August 3, 2016

Kossan International Sdn. Bhd.  
Cho Sow Fong  
RA Manager  
Wisma Kossan, Lot 782, Jalan Sungai Putus  
Off Batu 3 ¾, Jalan Kapar  
Klang, Selangor 42100  
MALAYSIA

Re: K151750

Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile. Tested for Use with Chemotherapy Drugs

Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile. Tested for Use with Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: Class I  
Product Code: LZA, LZC  
Dated: July 20, 2016  
Received: July 28, 2016

Dear Ms. Cho Sow Fong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

*Tejashri Purohit-Sheth, M.D.*

Tejashri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)  
K151750

Device Name

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe)

A patient examination glove 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 as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) (3.3 mg/ml)	10.1
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytosan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	30.2
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that Carmustine (BCNU) has extremely low permeation times of 10.1 minutes.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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

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

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### Indications for Use

510(k) Number (if known)  
K151750

Device Name

Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe)

A patient examination glove 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 as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) (3.3 mg/ml)	10.1
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytosan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	10.4
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that the following drugs have extremely low permeation times:  
Carmustine (BCNU) : 10.1 minutes and Thiotepa : 10.4 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)

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**FDA 510(k) Premarket Notification**  
**510(k) Summary of Safety and Effectiveness**

**Date Prepared: August 03, 2016**

**1.0 Submitter:**

**Kossan International Sdn. Bhd.**

Wisma Kossan, Lot 782, Jalan Sungai Putus,  
Off Batu 3 ¾, Jalan Kapar,  
42100 Klang, Selangor,  
Malaysia

Telephone No.: +603 3291 0516

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**2.0 Contact Person:**

Contact: Ms Cho Sow Fong

Telephone No.: +603 3291 0516

Fax No.: +603 3291 0542

**3.0 Name of Device:**

Trade Name(s) : 1. Powder Free Nitrile Patient Examination Glove,  
Blue Colored, Non-Sterile.  
Tested for Use with Chemotherapy Drugs  
2. Powder Free Nitrile Patient Examination Glove,  
White Colored, Non-Sterile.  
Tested for Use with Chemotherapy Drugs

Common Name : Powder-Free Nitrile Patient Examination Glove

Classification Name : Patient Examination Glove

Regulation Number : 21 CFR 880.6250

Classification Number: Class I

Product Code : LZA, LZC

**4.0 Identification of the Legally Marketed Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs, Class I Patient Examination Gloves, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate Devices:

K090412 - Powder Free Nitrile Examination Gloves (Pink, Green, Orange, White).  
This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole. Low  
Dermatitis Potential. Tested for Use with Chemotherapy Drugs.  
Product code: LZA, LZC

**5.0 Description of Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs, is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The gloves are made of Nitrile Butadiene Rubber, powder free, ambidextrous with beaded-cuff, blue or white colored, single-use disposable devices that come in six sizes (XS, S, M, L, XL, XXL), and supplied in Non-Sterile state.

These gloves were designed and manufactured per ASTM D6319-10 standard, and tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*.

The principle operating characteristic of the device is to prevent contamination between patient and examiner, achieving through conformance of barrier, physical properties and other testing requirements as stated in Section 7.0 of this 510(k) Summary.

These gloves comply with ASTM D6319-10 and ASTM D5151-11 on water leak test requirements, forming a barrier to prevent contamination between patient and examiner. Testing of the subject device shows it meets the 1.5 AQL for leakage, exceeding ASTM D6319-10 requirement of 2.5 AQL for leakage.

The physical properties of the subject devices meet the requirements for tensile strength and elongation (both unaged and aged) as stated in ASTM D6319-10 standard.

The results (summarized in Section 7.0) demonstrated that the subject devices meets various relevant established standards and are acceptable to for their intended use, to prevent contamination between patient and examiner.

**6.0 Intended Use of the Device:****6.1 Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs**

A patient examination glove 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 as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration    Minimum Breakthrough Detection Time in Minutes

<b>Carmustine (BCNU) (3.3 mg/ml)</b>	<b>10.1</b>
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytosan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (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 (Taxol) (6.0 mg/ml)	>240
<b>Thiotepa (10.0 mg/ml)</b>	<b>30.2</b>
Vincristine Sulfate (1.0 mg/ml)	>240

**Please note that Carmustine (BCNU) has extremely low permeation times of 10.1 minutes.**

## 6.2 **Device Name: Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs**

A patient examination glove 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 as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration    Minimum Breakthrough Detection Time in Minutes

<b>Carmustine (BCNU) (3.3 mg/ml)</b>	<b>10.1</b>
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine(100 mg/ml)	>240
Dacarbazine (DTIC) (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 (Taxol) (6.0 mg/ml)	>240
<b>Thiotepa (10.0 mg/ml)</b>	<b>10.4</b>
Vincristine Sulfate (1.0 mg/ml)	>240

**Please note that the following drugs have extremely low permeation times:**

**Carmustine (BCNU) : 10.1 minutes and Thiotepa : 10.4 minutes.**

## 7.0 **Summary of the Technological Characteristics of the Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs, processes the following technological characteristic (as compared to ASTM or equivalent standards) as shown in Table below.

Characteristic	Standards Requirements	Results Summary	Conclusions
Dimensions	ASTM D6319-10	Length $\geq 230\text{mm}$ Palm Thickness $\geq 0.05\text{mm}$ Finger Thickness $\geq 0.05\text{mm}$ Width X-Small 70-80mm Small 80-90mm Medium 90-100mm Large 101-111mm X-Large 111-121mm XX-Large 121-131mm	Meets Standard Requirements
Physical Properties	ASTM D6319-10	Tensile Strength $\geq 14\text{ MPA}$ Elongation $\geq 500\%$	Meets Standard Requirements
Freedom from pinholes	ASTM D5151-11 ASTM D6319-10	Tested in accordance with ASTM D5151 test method. Pass quality level at G1 AQL 1.5	Meets Standard Requirements
Powder Free Residue	ASTM D6124-11 ASTM D6319-10	Result generated values $\leq 2\text{ mg}$ of residual powder per glove.	Meets Standard Requirements
Biocompatibility	Dermal Sensitization (as ISO 10993-10:2010)	Magnusson & Kligman Scale is '0'. Under the conditions of the study, the device is not a sensitizer.	Meets Standard Requirements
	Primary Skin Irritation Test (as ISO 10993-10:2010)	Primary Irritation Index for Erythema and Edema is '0'. Under the conditions of the study, the device is not an irritant.	Meets Standard Requirements

Characteristic	Standards Requirements	Results Summary	Conclusions																														
Chemotherapy Drugs Permeation Test	ASTM D6978-05 (Reapproved 2013)	<p><b>Powder Free Nitrile Patient Examination Glove, <u>Blue</u> Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs</b></p> <p>Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)</p> <table border="0"> <tr> <td><b>Carmustine (BCNU) (3.3 mg/ml)</b></td> <td><b>10.1</b></td> </tr> <tr> <td>Cisplatin (1.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Cyclophosphamide (Cytosan) (20.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Cytarabine (100 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Dacarbazine (DTIC) (10.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Doxorubicin Hydrochloride (2.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Etoposide (20.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Fluorouracil (50.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Ifosfamide (50.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Methotrexate (25.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Mitomycin C (0.5 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Mitoxantrone (2.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td>Paclitaxel (Taxol) (6.0 mg/ml)</td> <td>&gt;240</td> </tr> <tr> <td><b>Thiotepa (10.0 mg/ml)</b></td> <td><b>30.2</b></td> </tr> <tr> <td>Vincristine Sulfate (1.0 mg/ml)</td> <td>&gt;240</td> </tr> </table>	<b>Carmustine (BCNU) (3.3 mg/ml)</b>	<b>10.1</b>	Cisplatin (1.0 mg/ml)	>240	Cyclophosphamide (Cytosan) (20.0 mg/ml)	>240	Cytarabine (100 mg/ml)	>240	Dacarbazine (DTIC) (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 (Taxol) (6.0 mg/ml)	>240	<b>Thiotepa (10.0 mg/ml)</b>	<b>30.2</b>	Vincristine Sulfate (1.0 mg/ml)	>240	<p>Tested for Use with Chemotherapy Drugs.</p> <p>Carmustine has extremely low permeation time of less than 30 minutes</p>
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## **8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs, have been tested against the applicable ASTM standards listed above, and meet the requirements set forth in those standards.

The subject device (Blue and White) have additional size in Double Extra Large compared with predicate K090412 (Pink, Green, Orange and White). The additional sizing provides greater range to cover people with Double Extra Large hand or finger to prevent contamination between patient and examiner. The additional sizing does not affect the safety and effectiveness of the subject device.

There is difference in colorant used in one of the subject device (Blue), compared with predicate K090412 (Pink, Green, Orange and White). The difference does not affect the safety and effectiveness of the subject device (Blue), as the subject device is tested and passed biocompatibility test, similar with predicate devices.

The subject device (Blue and White) were tested with 15 drugs respectively with results in minimum breakthrough time, while predicate K090412 (Pink, Green, Orange and White) was tested with 14 drugs with result in average breakthrough time. The respective drug's permeation result is shown in Indication for Use of the subject device.

The reporting in minimum instead of average breakthrough detection time does not affect the safety and effectiveness of the subject device (Blue and White). The extra drug tested enable users to be more informed on subject device's performance against additional chemotherapy drug tested.

The minimum breakthrough detection time of Carmustine for the subject device (Blue and White) is below 30 minutes, similar with predicate K090412 (Pink, Green, Orange and White).

The minimum permeation time of Thiotepa for subject device is at 30.2 minutes (Blue), and 10.4 minutes (White) respectively. Subject device (Blue) is having longer permeation time than predicate K090412 (Pink, Green, Orange and White); while subject device (White) permeation time is similar with predicate K090412 (Pink, Green, Orange and White), below 30 minutes.

Warning statement (Do Not Use with Carmustine and Thiotepa) for subject device (Blue and White) is included in Labeling, similar with predicate devices.

The subject device (Blue and White) are having similar thickness with predicate K090412 (Pink) at palm, and similar length with predicate K090412 (Pink, Green, Orange and White).

In addition, the subject device (Blue and White) tested is having longer permeation than predicate K090412 (Pink) for Cyclophosphamide (Cytosan) and Ifosfamide. The subject device (Blue and White) is also having longer permeation than predicate K090412 (Green) for Cyclophosphamide (Cytosan) and Ifosfamide.

The subject device (Blue and white) is having identical specification with predicate K090412 (Pink, Green, Orange and White) with thickness at minimum 0.05 mm and length at minimum 230 mm.

The subject device (Blue and White) was tested at cuff while predicate K090412 (Pink, Green, Orange and White) at palm.

The differences in labeling (with additional drug tested, reporting in minimum breakthrough time instead of average, testing location, and the permeation time) do not affect the safety and effectiveness of the subject device (Blue and White).

The subject device (Blue and White) and the predicate devices share the same intended use, same Nitrile material, and same compliant with ASTM standards. There is no difference between the subject device (Blue and White) and the predicate devices with respect to intended use, non-clinical performance data and technological characteristics.

Consequently, the gloves that are the subject of this submission are substantially equivalent to a legally marketed glove, K090412.

#### **9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data**

Clinical data was not needed.

#### **10.0 Substantial Equivalent Comparison Table**

The Substantial Equivalent Comparison Table below outlines the similarity, and/or differences between the subject device and the predicate device for the substantial equivalent determination.

**Substantial Equivalent Comparison Table**

Characteristics	Subject Device K151750		Predicate Device K090412				Comments
	Blue	White	Pink	Green	Orange	White	
Manufacturer	Kossan International Sdn Bhd		GX Corporation Sdn Bhd				N/A
510(k) Number	K151750		K090412				N/A
Identification	1. Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs 2. Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs		Powder Free Nitrile Examination Gloves (Pink, Green, Orange, White). This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole. Low Dermatitis Potential. Tested for Use with Chemotherapy Drugs.				N/A
Device Classification Name/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250		Patient Examination Glove/ 21 CFR Part 880.6250				Substantially Equivalent
Product Code	LZA, LZC		LZA, LZC				Substantially Equivalent
Intended Use	A patient examination glove 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 per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs		This glove is disposable and intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This glove is tested for use with Dacarbazine (DTIC), Mitomycin C, Methotrexate, Cyclophosphamide (Cytoxan), Mitoxantrone, Doxorubicin Hydrochloride, Ifosfamide (Ifex), 5-Fluorouracil, Cisplatin, Etoposide, Paclitaxel (Taxol), Vincristine Sulfate				Substantially Equivalent

Characteristics	Subject Device K151750		Predicate Device K090412				Comments
	Blue	White	Pink	Green	Orange	White	
Materials	Nitrile		Nitrile				Substantially Equivalent
Color	Blue, and White		Pink, Green, Orange, White				Substantially Equivalent Different color, except white. The difference does not raise any safety issues
Design	Extra Small Small Medium Large Extra Large Double Extra Large		Meet Requirements of ASTM D6319				Substantially Equivalent
Single Use	Yes		Yes				Substantially Equivalent
Sterility	Non-Sterile		Non-Sterile				Substantially Equivalent
Length	min 230 mm Meet Requirements of ASTM D6319		min 230 mm Meet Requirements of ASTM D6319				Substantially Equivalent
Thickness (mm)							
- Cuff	0.032-0.050	0.040-0.050	NA	NA	NA	NA	N/A
- Palm	<b>0.055-0.085</b>	<b>0.055-0.085</b>	<b>0.054-0.083</b>	0.073-0.094	0.072-0.086	0.072-0.094	Substantially Equivalent Meet Requirements of ASTM D6319
- Finger	0.065-0.095	0.065-0.095	NA	NA	NA	NA	N/A
Powder Free Residue	≤ 2mg/glove		≤ 2 mg/glove				Substantially Equivalent
Physical Properties	Meet Requirements of ASTM D6319		Meet Requirements of ASTM D6319				Substantially Equivalent

Characteristics	Subject Device K151750		Predicate Device K090412				Comments
	Blue	White	Pink	Green	Orange	White	
Biocompatibility Test	Passes i. Primary Skin Irritation Test – Not a primary skin irritant under the conditions of the study ii. Dermal Sensitization Test – Not a contact sensitizer under the conditions of the study		Passes i. Primary Skin Irritation Test ii. Dermal Sensitization Test				Substantially Equivalent
Packaging	Packed in Dispenser Boxes		Packed in Dispenser Boxes				Substantially Equivalent
Labeling Features	<ul style="list-style-type: none"> <li>- Non-sterile</li> <li>- Powder Free</li> <li>- Examination Gloves</li> <li>- Ambidextrous, by Size</li> <li>- Single Use Only</li> <li>- Device Color</li> <li>- Manufactured for:</li> <li>- Lot Number:</li> <li>- Quantity by Weight</li> <li>- Made in Malaysia</li> </ul>		<ul style="list-style-type: none"> <li>- Non-sterile</li> <li>- Powder Free</li> <li>- Examination Gloves</li> <li>- Ambidextrous, by Size</li> <li>- Single Use Only</li> <li>- Device Color</li> <li>- Manufactured for:</li> <li>- Lot Number:</li> <li>- Quantity by Weight</li> <li>- Made in Malaysia</li> </ul>				Substantially Equivalent

Characteristics	Subject Device K151750		Predicate Device K090412				Comments
	Blue	White	Pink	Green	Orange	White	
Chemotherapy Drugs Permeation Test							-
Chemotherapy Drugs (Concentration)	<b>Minimum Breakthrough Detection Time in Minutes</b>		<b>Average Breakthrough Detection Time in Minutes</b>				
Carmustine (BCNU) (3.3 mg/ml)	<b>10.1</b>	<b>10.1</b>	<b>0.44</b>	<b>0.72</b>	<b>1.34</b>	<b>5.16</b>	Substantially Equivalent <i>Below 30 minutes permeation time, similar with predicate devices</i>
Cisplatin (1.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Cyclophosphamide (Cytosan) (20.0 mg/ml)	<b>&gt; 240</b>	<b>&gt; 240</b>	<b>55.10</b>	<b>175.13</b>	> 240	> 240	Substantially Equivalent <i>Subject device (Blue and White) having longer permeation than predicate (Pink and Green)</i>
Cytarabine (100 mg/ml)	> 240	> 240	Not Tested				<b>Additional drug tested for subject device</b>
Dacarbazine (DTIC) (10.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Etoposide (20.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Fluorouracil (50.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Ifosfamide (50.0 mg/ml)	<b>&gt; 240</b>	<b>&gt; 240</b>	<b>68.13</b>	<b>160.85</b>	> 240	> 240	Substantially Equivalent <i>Subject device (Blue and White) having longer permeation than predicate (Pink and Green)</i>
Methotrexate (25.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Mitomycin C (0.5 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent

Characteristics	Subject Device K151750		Predicate Device K090412				Comments
	Blue	White	Pink	Green	Orange	White	
Chemotherapy Drugs Permeation Test							-
Chemotherapy Drugs (Concentration)	<b>Minimum Breakthrough Detection Time in Minutes</b>		<b>Average Breakthrough Detection Time in Minutes</b>				
Mitoxantrone (2.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Paclitaxel (Taxol) (6.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Thiotepa (10.0 mg/ml)	<b>30.2</b>	<b>10.4</b>	<b>3.46</b>	<b>2.39</b>	<b>2.26</b>	<b>3.06</b>	Substantially Equivalent <i>Subject device (Blue) at 30.2 minute; Subject device (White) below 30 minutes permeation time, similar with predicate (Pink, Green, Orange, White)</i>
Vincristine Sulfate (1.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Warning statement	<b>WARNING:</b> Do Not Use with Carmustine and Thiotepa		<b>WARNING:</b> Not recommended for use with Carmustine and Thiotepa <b>Caution:</b> the permeation time for Cyclo-phosphamide is only 55 minutes	<b>WARNING:</b> Not recommended for use with Carmustine and Thiotepa			Substantially Equivalent
Labeling Claim	<b>Tested for Use with Chemotherapy Drugs</b>		This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole. Low Dermatitis Potential. <b>Tested for Use with Chemotherapy Drugs.</b>			Subject device do not have claim of <i>This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole. Low Dermatitis Potential</i>	

## **11.0 Conclusion**

Based on intended uses, technological characteristics and non-clinical performance data, the subject device K151750 is substantially equivalent to the predicate device K090412.