



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

August 2, 2016

Kossan International Sdn. Bhd.  
Ms. Cho Sow Fong  
RA Manager  
Wisma Kossan, Lot 782, Jalan Sungai Putus  
Off Batu 3 3/4, Jalan Kapar  
42100 Klang, Selangor  
Malaysia

Re: K151824

Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs  
Powder Free Nitrile Patient Examination Glove, White Colored, Non-sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA, LZC  
Dated: July 20, 2016  
Received: July 25, 2016

Dear 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" (21 CFR 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 yours,

*Tejashri Purohit-Sheth, M.D.*

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

Tina Kiang, Ph.D.  
Acting 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)

K151824

Device Name

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile. Low Dermatitis Potential, and 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 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)	10.4
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)	90.5
Vincristine Sulfate (1.0 mg/ml)	>240

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

**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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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:

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Food and Drug Administration  
Office of Chief Information Officer  
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*"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."*

## Indications for Use

510(k) Number (if known)

**Device Name**

Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile. Low Dermatitis Potential, and 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 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)	10.3
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)	70.5
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that Carmustine (BCNU) has extremely low permeation times of 10.3 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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**FDA 510(k) Premarket Notification**  
**510(k) Summary of Safety and Effectiveness**

**Date Prepared: August 2, 2016 (TCK)**

**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

Fax No.: +603 3291 0542

**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. Low Dermatitis Potential, and  
Tested for Use with Chemotherapy Drugs  
2. Powder Free Nitrile Patient Examination Glove,  
White Colored, Non-Sterile. Low Dermatitis Potential, and  
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, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and 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:

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs – were previously cleared under 510(k) K120066 (product code LZA).

Predicate Device: **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

Predicate Device: **K102790** Powder-Free Nitrile Patient Examination Gloves, Blue, Non-Sterile (*Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim*); Product code: LZA, LZC

**5.0 Description of Device:**

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and 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.

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*, and Modified-Draize-95 Test, per FDA's guidance document "*Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products, 1999*".

The gloves are made of Nitrile Butadiene Rubber, powder free, ambidextrous (i.e. can be worn on right hand or left hand) with beaded cuff, blue or white colored, single-use disposable devices, that come in five sizes (XS, S, M, L, XL), and supplied in Non-Sterile state.

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.

The gloves are also complied with ASTM D6319-10 and ASTM D5151-11 on water leak test, 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 gloves are designed and manufactured in accordance with ASTM D6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application*. The physical properties of the subject device meet the requirements for tensile strength and elongation (both unaged and aged) in the 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. Low Dermatitis Potential, and 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 per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

<u>Chemotherapy Drug and Concentration</u>	<u>Minimum Breakthrough Detection Time in Minutes</u>
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<b>Carmustine (BCNU) (3.3 mg/ml)</b>	<b>10.4</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>90.5</b>
Vincristine Sulfate (1.0 mg/ml)	>240

**Please note that Carmustine (BCNU) has extremely low permeation times of 10.4 minutes.**

**6.2 Device Name: Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile. Low Dermatitis Potential, and 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 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>10.3</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>70.5</b>
Vincristine Sulfate (1.0 mg/ml)	>240

**Please note that Carmustine (BCNU) has extremely low permeation times of 10.3 minutes.**

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

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

Chemotherapy claim is similar to Predicate, which has a glove thickness below 0.10 mm and is shorter than 270mm but compliant with ASTM standards.

Characteristic	Standards Requirements	Results Summary	Conclusions
Dimensions	ASTM D6319-10	Length $\geq 240$ mm Palm Thickness $\geq 0.05$ mm Finger Thickness $\geq 0.05$ mm Width X-Small 70-80mm Small 80-90mm Medium 90-100mm Large 101-111mm X-Large 111-121mm	Meets Standard Requirements
Physical Properties	ASTM D6319-10	Tensile Strength $\geq 14$ MPA Elongation $\geq 500\%$	Meets Standard Requirements <u>Before Aging</u> $\geq 14$ MPA <u>After Aging</u> $\geq 14$ MPA $\geq 400\%$
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 $\leq 2$ 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
Low Dermatitis Potential	Modified Draize-95 Test	All 200 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase.  Under the conditions of the study, there was no clinical evidence of the presence of residual chemical additives that may induce Type IV allergy in the unsensitized general user population in the tested articles.	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, Blue Colored, Non-Sterile. Low Dermatitis Potential, and 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>10.4</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>90.5</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>10.4</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>90.5</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, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and 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.

Modified Draize-95 test completed on 200 non-sensitized adult human subjects that reasonably reflect the general user population in the US, gave all negative results. There was no clinical evidence of the presence of residue chemical additives at the level that may induce Type IV allergy in the un-sensitized general user population in the tested article.

Subject device (Blue and White) was previously cleared under K120066 without tested for used with chemotherapy drugs. Predicate K102790 is tested for use with chemotherapy drugs for Blue, while Predicate K090412 has four colors (Pink, Green, Orange, and White) tested for use with chemotherapy drugs.

The different in color does not affect the safety and effectiveness of the subject device, as the subject device (Blue and White) was tested and passed Biocompatibility test, and Modified Draize-95 test, similar with predicate devices.

The subject device were tested for 15 drugs for both Blue and White, while predicate device K102790 tested 9 drugs, and K090412 tested 14 drugs. The subject device is with results in minimum breakthrough time, while predicate K102790 and K090412 are with result in average breakthrough time.

The reporting in minimum instead of average breakthrough detection time does not affect the safety and effectiveness of the subject device. The extra drug tested enable users to be more informed on subject device's performance against additional chemotherapy drug tested. The respective drug's permeation result is shown in Indication for Use of the subject devices.

The minimum performance of Carmustine for the subject device (Blue and White) is below 30 minutes, similar with predicate K102790 and K090412. Warning statement (Not to be used with Carmustine) for subject device is included in Labeling, similar with predicate devices.

The minimum permeation time of Thiotepa for subject device is 90.5 minutes (Blue) and 70.5 minutes (White) respectively, similar with predicate K102790 permeation time at 72.36 minutes, both above 30 minutes and below 90 minutes; and longer than predicate K090412 (Pink, Green, Orange, White).

The subject device (Blue and White) are having similar thickness with Predicate K102790 (Blue), and thicker than K090412 (Pink) at palm. The subject device (Blue and White) are having similar length with Predicate K090412 (Pink, Green, Orange, White) at minimum 240 mm.

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) was tested at cuff while predicate K102790 and predicate K090412 (Pink, Green, Orange and White) at palm.

The differences in labeling (with additional drugs 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).

Chemotherapy claim is similar to Predicate K102790 and K090412 (Pink, Green, Orange, White), which has a glove thickness below 0.10 mm and is shorter than 270 mm but compliant with ASTM standards.

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, K102790 and K090412.

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

Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs; and Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs, were tested in accordance with Modified Draize-95 Test, per FDA's guidance document "Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products, 1999".

The study was conducted in two stages. In the first stage, a population of 50 human subjects was tested to evaluate the product for the potential to cause irritation or sensitization. The second stage was initiated on a further number of subjects to a total of a minimum of 200 individuals after the first stage has shown that the test product does not indicate a potential for inducing dermal irritation and does not shown sensitization capability.

The study completed on 200 non-sensitized adult human subjects, who reasonably reflect the general user population in the US, gave all negative results. There was no clinical evidence of the presence of residual chemical additives at the level that may induce Type IV allergy in the un-sensitized general user population in the tested article.

## **10.0 Conclusion**

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.

Based on intended uses, technological characteristics and non-clinical performance data, the subject device K151824 is substantially equivalent to the predicate devices K102790 and K090412.

**Substantial Equivalent Comparison Table**

Characteristics	Subject Device		Predicate Device 1	Predicate Device 2				Comments
	Blue	White	Blue	Pink	Green	Orange	White	
Manufacturer	Kossan International Sdn Bhd		Perusahaan Getah Asas Sdn Bhd	GX Corporation Sdn. Bhd.				N/A
510(k) Number	<b>K151824</b>		<b>K102790</b>	<b>K090412</b>				N/A
Identification	1. Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile. <b>Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs</b> 2. Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile. <b>Low Dermatitis Potential, and Tested for Use with Chemotherapy Drugs</b>		Powder-Free Nitrile Patient Examination Gloves, Blue, Non-Sterile ( <b>Low Dermatitis Potential and Chemotherapy Drugs Protection Labeling Claim</b> )	Powder Free Nitrile Examination Gloves (Pink, Green, Orange, White). <b>This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole. Low Dermatitis Potential. Tested for Use with Chemotherapy Drugs.</b>				N/A
Device Classification Name/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250		Patient Examination Glove/ 21 CFR Part 880.6250	Patient Examination Glove/ 21 CFR Part 880.6250				Substantially Equivalent
Product Code	LZA, LZC		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 a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.  This glove has been tested for use with specific 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 (Cytosan), Mitoxantrone, Doxorubicin Hydrochloride, Ifosfamide (Ifex), 5-Fluorouracil, Cisplatin, Etoposide, Paclitaxel (Taxol), Vincristine Sulfate				Substantially Equivalent

Characteristics	Subject Device K151824		Predicate Device 1 K102790	Predicate Device 2 K090412				Comments
	Blue	White	Blue	Pink	Green	Orange	White	
Materials	Nitrile		Nitrile	Nitrile				Substantially Equivalent
Color	<b>Blue, and White</b>		<b>Blue</b>	<b>Pink, Green, Orange, White</b>				Subject device available in Blue and White Color
Design	Extra Small Small Medium Large Extra Large		Extra Small Small Medium Large Extra Large	Meet Requirements of ASTM D6319				Substantially Equivalent
Single Use	Yes		Yes	Yes				Substantially Equivalent
Sterility	Non-Sterile		Non-Sterile	Non-Sterile				Substantially Equivalent
Length	Min 240 mm Meet Requirements of ASTM D6319		Min 240 mm Meet Requirements of ASTM D6319	Min 230 mm Meet Requirements of ASTM D6319				Substantially Equivalent
Thickness (mm)								N/A
- Cuff	0.052-0.058	0.053-0.063	NA	NA	NA	NA	NA	
- Palm	<b>0.065-0.085</b>	<b>0.065-0.085</b>	<b>0.065-0.074</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	0.075-0.095	0.075-0.095	NA	NA	NA	NA	NA	N/A
Powder Free Residue	≤ 2mg/glove		≤ 2 mg/glove	≤ 2 mg/glove				Substantially Equivalent
Physical Properties	Meet Requirements of ASTM D6319		Meet Requirements of ASTM D6319	Meet Requirements of ASTM D6319				Substantially Equivalent

Characteristics	Subject Device K151824		Predicate Device 1 K102790	Predicate Device 2 K090412				Comments
	Blue	White	Blue	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 – Not a primary skin irritant ii. Dermal Sensitization Test – Not a contact sensitizer	Passes i. Primary Skin Irritation Test – Not a primary skin irritant ii. Dermal Sensitization Test – Not a contact sensitizer				Substantially Equivalent
Modified Draize Test	Under the conditions of the study, there was no clinical evidence of the presence of residual chemical additives that may induce Type IV allergy in the un-sensitized general user population in the tested articles.		Under the conditions of a repeated insult (occlusive) patch test procedure, test article was ‘Dermatologist-Tested’ and did not induce clinically significant skin irritation nor show any evidence of induced allergic contact dermatitis in human subjects.	There is no clinical evidence of the presence of residual chemical additives at the level that may induce Type IV allergy in the un-sensitized general user population in the tested articles.				Substantially Equivalent
Packaging	Packed in Dispenser Boxes		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>	<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 K151824		Predicate Device 1 K102790	Predicate Device 2 K090412				Comments
	Blue	White	Blue	Pink	Green	Orange	White	
Labeling Claim	1. Low Dermatitis Potential 2. Tested for Use with Chemotherapy Drugs		1. Low Dermatitis Potential 2. Chemotherapy Drugs Protection Labeling Claim	1. Low Dermatitis Potential 2. Tested For Use with Chemotherapy Drugs 3. This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole.				Substantially Equivalent  - Predicate device 2 K090412 has additional claim on <i>“This Product Does Not Contain Thiuram, and/or Carbamate and/or Thiazole”</i>

Characteristics	Subject Device K151824		Predicate 1 K102790	Predicate 2 K090412				Comments
	Blue	White	Blue	Pink	Green	Orange	White	
Chemotherapy Drugs Permeation Test								-
Chemotherapy Drugs (Concentration)	Minimum Breakthrough Detection Time in Minutes		Average Breakthrough Detection Time in Minutes					-
Carmustine (BCNU) (3.3 mg/ml)	<b>10.4</b>	<b>10.3</b>	<b>16.70</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	> 240	Substantially Equivalent
Cyclophosphamide (Cytosan) (20.0 mg/ml)	> <b>240</b>	> <b>240</b>	> 240	<b>55.10</b>	<b>175.13</b>	> 240	> 240	Substantially Equivalent <i>Subject device (Blue and White) having longer permeation than predicate K090412(Pink and Green)</i>
Cytarabine (100 mg/ml)	> <b>240</b>	> <b>240</b>	Not Tested	Not Tested				<b>Additional drug tested for subject device</b>
Dacarbazine (DTIC) (10.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Etoposide (20.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Fluorouracil (50.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Ifosfamide (50.0 mg/ml)	> <b>240</b>	> <b>240</b>	Not Tested	<b>68.13</b>	<b>160.85</b>	> 240	> 240	Substantially Equivalent <i>Subject device (Blue and White) having longer permeation than predicate K090412(Pink and Green)</i>
Methotrexate (25.0 mg/ml)	> 240	> 240	Not Tested	> 240	> 240	> 240	> 240	Substantially Equivalent

Characteristics	Subject Device K151824		Predicate 1 K102790	Predicate 2 K090412				Comments
	Blue	White	Blue	Pink	Green	Orange	White	
Chemotherapy Drugs Permeation Test								-
Chemotherapy Drugs (Concentration)	Minimum Breakthrough Detection Time in Minutes		Average Breakthrough Detection Time in Minutes					
Mitomycin C (0.5 mg/ml)	> 240	> 240	Not Tested	> 240	> 240	> 240	> 240	Substantially Equivalent
Mitoxantrone (2.0 mg/ml)	> 240	> 240	Not Tested	> 240	> 240	> 240	> 240	Substantially Equivalent
Paclitaxel (Taxol) (6.0 mg/ml)	> 240	> 240	> 240	> 240	> 240	> 240	> 240	Substantially Equivalent
Thiotepa (10.0 mg/ml)	<b>90.5</b>	<b>70.5</b>	<b>72.36</b>	<b>3.46</b>	<b>2.39</b>	<b>2.26</b>	<b>3.06</b>	Substantially Equivalent <i>Similar with Predicate K102790, at range of 30 and 90 minutes, and longer than predicate K090412.</i>
Vincristine Sulfate (1.0 mg/ml)	> 240	> 240	Not Tested	> 240	> 240	> 240	> 240	Substantially Equivalent
Warning statement	<b>WARNING:</b> Not to be used with Carmustine.		Please note that Carmustine has extremely low permeation times of less than 30 minutes.	<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	