DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

YTY Industry (Manjung) Sdn. Bhd.,
Punitha Samy
Deputy Manager-DC/RA
Lot 1422-1424
Batu 10 Lekir
Sitiawan, Perak 32020 MY

Re: K162095
Trade/Device Name: Non-sterile, Powder Free Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs (Original Blue, Cobalt Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: September 19, 2016
Received: September 23, 2016

Dear Punitha Samy:

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,

Michael J. Ryan -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K162095

Device Name

Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - Original Blue

Indications for Use *(Describe)*

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This glove is also tested for use against Chemotherapy Drugs. The Chemotherapy Drugs and its permeation time is listed as below.

| Tested Chemotherapy Drug And Concentration | Average Breakthrough Detection Time |
|---|---|
| Carboplatin, 10 mg/ml | > 240 minutes |
| Carmustine (3.3 mg/ml) | 1.84 minutes |
| Cisplatin (BCNU), 1.0 mg/ml | > 240 minutes |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml | > 240 minutes |
| Dacarbazine (DTIC), 10.0 mg/ml | > 240 minutes |
| Doxorubicin Hydrochloride, 2.0 mg/ml | > 240 minutes |
| Etoposide (Toposar), 20.0 mg/ml | > 240 minutes |
| Fluorouracil, 50.0 mg/ml | > 240 minutes |
| Ifosfamide , 50.0 mg/ml | > 240 minutes |
| Methotrexate, 25 mg/ml | > 240 minutes |
| Mitomycin C, 0.5 mg/ml | > 240 minutes |
| Mitoxantrone, 2 mg/ml | > 240 minutes |
| Paclitaxel (Taxol), 6.0 mg/ml | > 240 minutes |
| ThioTEPA (10.0 mg/ml) | 0.76 minutes |
| Vincristine Sulfate, 1.0 mg/ml | > 240 minutes |

The following chemotherapy drugs and concentration have extremely low permeation time.
Carmustine (3.3 mg/ml): 1.84 minutes ThioTEPA (10.0 mg/ml): 0.76 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162095

Device Name
Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - Cobalt Blue

Indications for Use *(Describe)*

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This glove is also tested for use against Chemotherapy Drugs. The Chemotherapy Drugs and its permeation time is listed as below.

| Tested Chemotherapy Drug And Concentration | Average Breakthrough Detection Time |
|---|---|
| Carboplatin, 10 mg/ml | > 240 minutes |
| Carmustine (3.3 mg/ml) | 1.82 minutes |
| Cisplatin (BCNU), 1.0 mg/ml | > 240 minutes |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml | > 240 minutes |
| Dacarbazine (DTIC), 10.0 mg/ml | > 240 minutes |
| Doxorubicin Hydrochloride, 2.0 mg/ml | > 240 minutes |
| Etoposide (Toposar), 20.0 mg/ml | > 240 minutes |
| Fluorouracil, 50.0 mg/ml | > 240 minutes |
| Ifosfamide , 50.0 mg/ml | > 240 minutes |
| Methotrexate, 25 mg/ml | > 240 minutes |
| Mitomycin C, 0.5 mg/ml | > 240 minutes |
| Mitoxantrone, 2 mg/ml | > 240 minutes |
| Paclitaxel (Taxol), 6.0 mg/ml | > 240 minutes |
| ThioTEPA (10.0 mg/ml) | 0.93 minutes |
| Vincristine Sulfate, 1.0 mg/ml | > 240 minutes |

The following chemotherapy drugs and concentration have extremely low permeation time.
Carmustine (3.3 mg/ml): 1.82 minutes ThioTEPA (10.0 mg/ml): 0.93 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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510 (K) SUMMARY SHEETS

**1.0** **510 (K) SUMMARY**

**2.0** Submitter

YTY INDUSTRY (MANJUNG) SDN. BHD.,
Lot 1422-1424, Batu 10 Lekir
32020 Sitiawan, Perak
Malaysia

Tel 605-6908533
Fax 605-6908533
Name of Contact Person Punitha Samy (Ms)
E-mail: punitha.samy@ytygroup.com.my

Date Summary Prepared November 2, 2016

**3.0 Name of Device**

Trade Name: Non-Sterile, Powder Free Blue Nitrile Patient Examination Gloves, Tested for use with Chemotherapy Drugs (Original Blue, Cobalt Blue)
Common Name: Nitrile Examination Gloves
Classification Name: Patient Examination Gloves, Powder Free
Device Classification: I

Regulation No. & Classification Name: Patient Examination Gloves Specialty (21 CFR 880.6250 product code LZC)
Patient Examination Gloves (21 CFR 880.6250 product code LZA)

Panel: General Hospital

**4.0 Identification of The Legally Marketed Devices that equivalency is claimed:**

| Device Name | Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs | Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs - Violet Blue (VBLU) |
|---|---|---|
| Predicate 510(K) number: | K141982 | K151997 |
| Device Classification: | 1 | 1 |
| Product Code: | LZC | LZC |

## 5.0 Description of The Device

Non-Sterile, Powder Free Blue Nitrile Patient Examination Gloves, Tested for use with Chemotherapy Drugs (Original Blue, Cobalt Blue) meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application and D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs and FDA 21 CFR 880.6250. The principle operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the counter single use.

## 6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This glove is also tested for use against Chemotherapy Drugs. The Chemotherapy Drugs and its permeation time is listed as below.

| Characteristic | Concentration | K162095<br>Original Blue | K162095<br>Cobalt Blue |
|---|---|---|---|
| | | Average Breakthrough Detection Time (minutes) | |
| Carboplatin | 10mg/ml | > 240 | > 240 |
| *Carmustine | 3.3mg/ml | 1.84 | 1.82 |
| Cisplatin (BCNU) | 1.0mg/ml | > 240 | > 240 |
| Cyclophosphamide (Cytoxan) | 20.0mg/ml | > 240 | > 240 |
| Dacarbazine (DTIC) | 10.0mg/ml | > 240 | > 240 |
| Doxorubicin Hydrochloride | 2.0mg/ml | > 240 | > 240 |
| Etoposide (Toposar) | 20.0mg/ml | > 240 | > 240 |
| Fluorouracil | 50.0mg/ml | > 240 | > 240 |
| Ifosfamide | 50.0mg/ml | > 240 | > 240 |
| Methotrexate | 25mg/ml | > 240 | > 240 |
| Mitomycin C | 0.5mg/ml | > 240 | > 240 |
| Mitoxantrone | 2 mg/ml | > 240 | > 240 |
| Paclitaxel (Taxol) | 6.0mg/ml | > 240 | > 240 |
| Thiotepa | 10.0mg/ml | 0.76 | 0.93 |
| Vincristine Sulfate | 1.0mg/ml | > 240 | > 240 |
| Warning Statement | | *WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 1.84 minutes and ThioTepa: 0.76 minutes. NOT TO BE USED WITH CARMUSTINE OR THIOTEPA | * WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 1.82 minutes and ThioTepa: 0.93 minutes. NOT TO BE USED WITH CARMUSTINE OR THIOTEPA |

## 7.0 Summary of the Technological Characteristic of the Device compared to the Predicate Device for substantial equivalent discussion

There is no difference in technology characteristic compared to the predicate device. Gloves are made from nitrile latex compound. Non-Sterile, Powder Free Blue Nitrile Patient Examination Gloves, Tested for use with Chemotherapy Drugs (Original Blue, Cobalt Blue) have the below technological characteristic compared to ASTM or Equivalent standards.

This glove is compliant with the ASTM standards and similar to the predicate device in the market, which has a glove thickness less than 0.10mm and length less than 270mm. The chemotherapy claim is similar to Predicate.

**Table 1 – Predicate 1**

| Characteristic | | Standards | Device Performance | |
|---|---|---|---|---|
| | | | Predicate | K162095 – Original Blue |
| 510(K) Number | | | K141982 | K162095 |
| Dimension | | ASTM D6319-10 | Min 240mm | Min 240mm |
| Physical Properties | | ASTM D6319-10 | Meets | Meets |
| Thickness | Finger<br>Palm<br>Cuff | ASTM D6319-10 | 0.07 – 0.10mm<br>0.07 – 0.09mm<br>0.06 – 0.08mm | 0.09 – 0.14mm<br>0.07 – 0.10mm<br>0.06 - 0.09mm |
| Powder-free | | ASTM D6124-06<br>(≤ 2mg/glove) | Meets | Meets |
| Bio-compatibility | | Primary skin irritation<br>ISO 10993-10 (2010) | Not a primary skin irritant under the conditions of the study | Under the condition of the study the device is non-irritant |
| | | Dermal Sensitization<br>ISO 10993-10 (2010) | Not a contact sensitizer under the conditions of the study | Under the condition of the study the device is non-sensitizer |

**Table 2 – Predicate 1**

| Characteristic | Tested according to ASTM D6978-05 | Device Performance | |
|---|---|---|---|
| | | Predicate-K141982 | K162095– Original Blue |
| | | Average Breakthrough Detection Time (minutes) | |
| | Concentration | Predicate | Current |
| Carboplatin | 10mg/ml | - | > 240 |
| *Carmustine | 3.3mg/ml | 15 | 1.84 |
| Cisplatin | 1.0mg/ml | > 240 | > 240 |
| Cyclophosphamide (Cytoxan) | 20.0mg/ml | > 240 | > 240 |
| Dacarbazine (DTIC) | 10.0mg/ml | > 240 | > 240 |
| Doxorubicin Hydrochloride | 2.0mg/ml | > 240 | > 240 |
| Etoposide (Toposar) | 20.0mg/ml | > 240 | > 240 |
| Fluorouracil | 50.0mg/ml | > 240 | > 240 |
| Ifosfamide (Ifex) | 50.0mg/ml | > 240 | > 240 |
| Methotrexate | 25mg/ml | - | > 240 |
| Mitomycin C | 0.5mg/ml | - | > 240 |
| Mitoxantrone | 2 mg/ml | > 240 | > 240 |
| Paclitaxel (Taxol) | 6.0mg/ml | > 240 | > 240 |
| Thiotepa | 10.0mg/ml | 2.0 | 0.76 |
| Vincristine Sulfate | 1.0mg/ml | > 240 | > 240 |
| Warning Statement | | *WARNING: Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes | *WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 1.84 minutes and ThioTepa: 0.76 minutes. NOT TO BE USED WITH CARMUSTINE OR THIOTEPA |

**Table 3 – Predicate 2**

| Characteristic | | Standards | Device Performance | |
|---|---|---|---|---|
| | | | Predicate | K162095 – Cobalt Blue |
| 510(K) Number | | | K151997 | K162095 |
| Dimension | | ASTM D6319-10 | Min 240mm | Min 240mm |
| Physical Properties | | ASTM D6319-10 | Meets | Meets |
| Thickness | Finger<br>Palm<br>Cuff | ASTM D6319-10 | 0.10min<br>0.07 – 0.09mm<br>- | 0.10min<br>0.07 – 0.09mm<br>0.05 - 0.08mm |
| Powder-free | | ASTM D6124-06 (≤ 2mg/glove) | Meets | Meets |
| Bio-compatibility | | Primary skin irritation ISO 10993-10 (2010) | Not a primary skin irritant under the conditions of the study | Under the condition of the study the device is non-irritant |
| | | Dermal Sensitization ISO 10993-10 (2010) | Not a contact sensitizer under the conditions of the study | Under the condition of the study the device is non-sensitizer |

**Table 4 – Predicate 2**

| Characteristic | Tested according to ASTM D6978-05 | Device Performance | |
|---|---|---|---|
| | | Predicate – K151997 | K162095 – Cobalt Blue |
| | | Average Breakthrough Detection Time (minutes) | |
| | Concentration | Predicate | Current |
| Carboplatin | 10mg/ml | - | > 240 |
| *Carmustine | 3.3mg/ml | 10.2 | 1.82 |
| Cisplatin | 1.0mg/ml | > 240 | > 240 |
| Cyclophosphamide (Cytoxan) | 20.0mg/ml | > 240 | > 240 |
| Dacarbazine (DTIC) | 10.0mg/ml | > 240 | > 240 |
| Doxorubicin Hydrochloride | 2.0mg/ml | > 240 | > 240 |
| Etoposide (Toposar) | 20.0mg/ml | > 240 | > 240 |
| Fluorouracil | 50.0mg/ml | > 240 | > 240 |
| Ifosfamide (Ifex) | 50.0mg/ml | - | > 240 |
| Methotrexate | 25mg/ml | > 240 | > 240 |
| Mitomycin C | 0.5mg/ml | > 240 | > 240 |
| Mitoxantrone | 2 mg/ml | - | > 240 |
| Paclitaxel (Taxol) | 6.0mg/ml | > 240 | > 240 |
| Thiotepa | 10.0mg/ml | 30.2 | 0.93 |
| Vincristine Sulfate | 1.0mg/ml | > 240 | > 240 |
| Warning Statement | | * Please note that Carmustine and Thiotepa have extremely low permeation times of 10.2 minutes and 30.2 minutes | * WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 1.82 minutes and ThioTepa: 0.93 minutes. NOT TO BE USED WITH CARMUSTINE OR THIOTEPA |

**Table 5**

| **Characteristics** | **Device Performance** | | | | |
|---|---|---|---|---|---|
| | **Predicate** K141982 | **K162095 Original Blue** | **Predicate K151997** | **K162095 Cobalt Blue** | **Medical Glove Manual (1661) and Standards** |
| Water tightness (1000ml) | Passes | Passes | Passes | Passes | ASTM D5151-06 |
| Color | Blue | Original Blue | Violet Blue | Cobalt Blue | |
| Material | Nitrile | Nitrile | Nitrile | Nitrile | ASTM D6319-10 (Reapproved 2015) |
| Size | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Extra Small<br>Small<br>Medium<br>Large<br>Extra Large | Labeling |
| Texture | Finger Textured | Finger Textured | Finger Textured | Finger Textured | |
| Single Use | Single Use | Single Use | Single Use | Single Use | Labeling |
| Bio-compatibility | Passes<br><br>Not primary skin irritant under the conditions of the study. | Passes<br><br>Under the condition of the study the device is non-irritant | Passes<br><br>Under the condition of the study the device is non-irritant | Passes<br><br>Under the condition of the study the device is non-irritant | Primary Skin Irritation -<br><br>ISO 10993-10: 2010(E) Test for Irritation and Skin Sensitization & Consumer Product Safety Commission II, Part 1500 |
| | Passes<br><br>Not a contact sensitizer under the conditions of the study. | Passes<br><br>Under the condition of the study the device in non-sensitizer | Passes<br><br>Under the condition of the study the device in non-sensitizer | Passes<br><br>Under the condition of the study the device in non-sensitizer | Dermal Sensitization –<br><br>ISO 10993-10(E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4) |

<table>
<tr>
<td>Indications for Use</td>
<td>A patient Examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.</td>
<td colspan="2">A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner’s hand or finger to prevent contamination between patient and examiner. This glove is also tested for use against Chemotherapy<br>Drugs. The Chemotherapy Drugs and its permeation time is listed as below.</td>
<td>Is nonsterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs.</td>
<td colspan="2">A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner’s hand or<br>finger to prevent contamination between patient and examiner. This glove is also tested for use against Chemotherapy<br>Drugs. The Chemotherapy Drugs and its permeation time is listed as below.</td>
<td>This gloves meet all current specifications listed under ASTM specifications D6319-10</td>
</tr>
<tr>
<td rowspan="3"></td>
<td rowspan="3">*Carmustine3.3mg/ml15<br>Cisplatin 1.0mg/ml > 240<br>Cyclophosphamide Cytoxan) 20.0mg/ml > 240<br>Dacarbazine (DTIC) 10.0mg/ml > 240<br>Doxorubicin Hydrochloride 2.0mg/ml> 240<br>Etoposide (Toposar) 20.0mg/ml > 240<br>Fluorouracil 50.0mg/ml> 240<br>Ifosfamide (Ifex) 50.0mg/ml> 240<br>Mitoxantrone 2 mg/ml> 240<br>Paclitaxel (Taxol) 6.0mg/ml> 240<br>Thiotepa 10.0mg/ml 2.0<br>Vincristine Sulfate 1.0mg/ml> 240<br><br>Warning Statement<br>*WARNING: Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes</td>
<td>Tested Chemotherapy Drug And Concentration</td>
<td>Average Break through Detection Time</td>
<td rowspan="3">Carmustine (3.3 mg/ml) 10.2 minutes<br>Cisplatin (1.0 mg/ml) >240 minutes<br>Cyclophosphamide (20 mg/ml) >240 minutes<br>Dacarbazine (10.0 mglml) >240 minutes<br>Doxorubicin Hydrochloride (2.0 mg/ml) >240 minutes<br>Etoposide (20.0 mg/ml) >240 minutes<br>Fluorouracil (50.0 mg/ml) >240 minutes<br>Methotrexate (25 mg/ml) >240 minutes<br>Mitomycin C (0.5 mg/ml) >240 minutes<br>Paclitaxel (6.0 mg/ml) >240 minutes<br>Thiotepa (10.0 mg/ml) 30.2 minutes<br>Vincristine Sulfate (1.0 mg/ml) >240 minutes<br><br>Please note that Carmustine and Thiotepa have extremely low permeation times of 10.2 minutes and 30.2 minutes.</td>
<td>Tested Chemotherapy Drug And Concentration</td>
<td>Average Break through Detection Time</td>
<td></td>
</tr>
<tr>
<td>Carboplatin, 10 mg/ml<br>Carmustine (3.3 mg/ml)<br>Cisplatin (BCNU), 1.0 mg/ml<br>Cyclophosphamide (Cytoxan), 20.0 mg/ml<br>Dacarbazine (DTIC), 10.0 mg/ml<br>Doxorubicin Hydrochloride, 2.0 mg/ml<br>Etoposide (Toposar), 20.0 mg/ml<br>Fluorouracil, 50.0 mg/ml<br>Ifosfamide , 50.0 mg/ml<br>Methotrexate, 25 mg/ml<br>Mitomycin C, 0.5 mg/ml<br>Mitoxantrone, 2 mg/ml<br>Paclitaxel (Taxol), 6.0 mg/ml<br>ThioTEPA (10.0 mg/ml)<br>Vincristine Sulfate, 1.0 mg/ml</td>
<td>>240 min<br>1.84 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>0.76 min<br>>240 min</td>
<td>Carboplatin, 10mg/ml<br>Carmustine (3.3 mg/ml)<br>Cisplatin (BCNU), 1.0 mg/ml<br>Cyclophosphamide (Cytoxan), 20.0 mg/ml<br>Dacarbazine (DTIC), 10.0 mg/ml<br>Doxorubicin Hydrochloride, 2.0 mg/ml<br>Etoposide (Toposar), 20.0 mg/ml<br>Fluorouracil, 50.0 mg/ml<br>Ifosfamide , 50.0 mg/ml<br>Methotrexate, 25 mg/ml<br>Mitomycin C, 0.5 mg/ml<br>Mitoxantrone, 2 mg/ml<br>Paclitaxel (Taxol), 6.0 mg/ml<br>ThioTEPA (10.0 mg/ml)<br>Vincristine Sulfate, 1.0 mg/ml</td>
<td>>240 min<br>1.82 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>>240 min<br>0.93 min<br>>240 min</td>
<td></td>
</tr>
<tr>
<td>The following chemotherapy drugs and concentration have extremely low permeation time.<br>Carmustine (3.3 mg/ml): 1.84 min<br>ThioTEPA (10.0 mg/ml): 0.76 min</td>
<td>The following chemotherapy drugs and concentration have extremely low permeation time.<br>Carmustine (3.3 mg/ml): 1.82 min<br>ThioTEPA (10.0 mg/ml): 0.93 min</td>
<td></td>
</tr>
</table>

## 8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The non-clinical tests performance data support a determination of substantial equivalence is the same as and in compliance to ASTM requirements.

## 9.0 Conclusion

The conclusions drawn from the intended uses, technological characteristics and non-clinical tests demonstrate that the subject device is substantially equivalent to the predicate device K141982 and K151997.