May 17, 2023

Hartalega NGC SDN. BHD.
Nurul Aisyah Kong
General Manager-Quality Assurance
No. 1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
Sepang, Selangor Darul Ehsan 43900
Malaysia

Re: K223437
Trade/Device Name: Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: March 15, 2023
Received: March 20, 2023

Dear Nurul Aisyah Kong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K223437

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

Indications for Use *(Describe)*
Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour) is a non-sterile 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 and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
5-Azacytidine (25.0 mg/ml)	> 240
Carboplatin (10.0 mg/ml)	> 240
Carmustine (3.3 mg/ml)	12.1
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Doxetacel (10.0 mg/ml)	> 240
Doxorubicin HCI (2.0 mg/ml)	> 240
Epirubicin (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Gemcitabine (38.0 mg/ml)	> 240
Ifosfamide (50.0 mg/ml)	> 240
Irinotecan (20.0 mg/ml)	> 240
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Mitoxantrone (2.0 mg/ml)	> 240
Oxalipatin (5.0 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	37.8
Vincristine Sulfate (1.0 mg/ml)	> 240
Oncovin (1.0 mg/ml)	> 240
Vinorelbine (10.0mg/ml)	> 240

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100mcg/2ml)	>240

Caution: Please note that Carmustine and Thiotepa have extremely low permeation times of 12.1 minutes and 37.8 minutes.
Warning: Do not use with Carmustine.

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

K223437

BIODEGRADABLE NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL CITRATE (FUSION COLOUR)

(The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92)

SUBMISSION APPLICANT

Date Prepared	:	May 15, 2023
Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, Sepang, Selangor Darul Ehsan, 43900 Malaysia
Establishment Registration Number	:	3011200663

SUBMISSION CORRESPONDENT AND/OR PREPARER

Contact Name	:	Nurul Aisyah Kong
Contact Title	:	General Manager – Quality Assurance
Phone Number	:	(603) 3280 3888
Fax Number	:	(603) 3271 0135
Contact Email	:	wkkong@hartalega.com.my

DEVICE IDENTIFICATION

Common Name of the Device	:	Non-Powdered Patient Examination Glove
Trade Name (Proprietary Name)	:	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)
Device Class	:	1
Product Code	:	LZA, LZC, QDO, OPJ
Regulation Number	:	21 CFR 880.6250
Reason for 510(k) Submission	:	New device

PREDICATE DEVICE INFORMATION

510(k) Number	Tradename	Product Code
K200581	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	LZA. LZC, QDO

Regulation Name	:	Non-Powdered Patient Examination Glove
Trade Name (Proprietary Name)	:	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)
Device Class	:	1
Product Code	:	LZA, LZC, QDO, OPJ
Regulation Number	:	21 CFR 880.6250

DESCRIPTION OF THE DEVICE:

Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour) is a disposable single-use, non-sterile, fusion-colored and powder-free examination glove made from nitrile latex.

INDICATIONS FOR USE:

Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour) is a non-sterile 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 and Fentanyl Citrate.

The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
5- Azacytidine, 25.0 mg/ml	> 240
Carboplatin, 10.0 mg/ml	> 240
Carmustine (3.3 mg/ml)	12.1
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Docetaxel, 10.0 mg/ml	> 240
Doxorubicin HCL (2.0 mg/ml)	> 240
Epirubicin, 2.0 mg/ml	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Gemcitabine, 38.0 mg/ml	> 240
Ifosfamide, 50.0 mg/ml	> 240
Irinotecan, 20.0 mg/ml	> 240
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Mitoxantrone, 2.0 mg/ml	> 240
Oxaliplatin, 2.0 mg/ml	> 240
Paclitaxel (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	37.8
Vincristine Sulfate (1.0 mg/ml)	> 240
Oncovin (1.0 mg/ml)	> 240
Vinorelbine, 10.0 mg/ml	> 240
Fentanyl Citrate, 100.0 mcg/2ml	> 240

Caution: Please note that Carmustine and Thiotepa have extremely low permeation times of 12.1 minutes and 37.8 minutes.

Warning: Do not use with Carmustine.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

Characteristics and Parameters	Subject Device	Predicate Device (K200581)	Discussion
Trade Name	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Colour)	Biodegradable Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	-
Applicant	Hartalega NGC Sdn. Bhd.	Hartalega NGC Sdn. Bhd.	Same
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO	Similar
Classification	1	1	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Regulation Name	Non-Powdered Patient Examination Glove	Non-Powdered Patient Examination Glove	Same
Indications for Use	A non-sterile 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 and Fentanyl Citrate. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	A non-sterile 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 and Fentanyl Citrate. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Similar

Characteristics and Parameters	Subject Device		Predicate Device (K200581)		Discussion
Test Chemotherapy Drugs	**Chemotherapy Drug and Concentration**	**Minimum Breakthrough Detection Time in Minutes**	**Chemotherapy Drug Concentration**	**Minimum Breakthrough Detection Time in Minutes**	Similar
	5-Azacytidine, 25.0mg/ml	> 240	5-Azacytidine, 25.0mg/ml	> 240	
	Carboplatin, 10.0 mg/ml	> 240	Carboplatin, 10.0 mg/ml	> 240	
	Carmustine (3.3 mg/ml)	12.1	Carmustine (3.3 mg/ml)	21.4	
	Cisplatin (1.0 mg/ml)	> 240	Cisplatin (1.0 mg/ml)	> 240	
	Cyclophosphamide (20.0 mg/ml)	> 240	Cyclophosphamide (20.0 mg/ml)	> 240	
	Dacarbazine (10.0 mg/ml)	> 240	Dacarbazine (10.0 mg/ml)	> 240	
	Docetaxel, 10.0 mg/ml	> 240	Docetaxel, 10.0 mg/ml	> 240	
	Doxorubicin HCL (2.0 mg/ml)	> 240	Doxorubicin HCL (2.0 mg/ml)	> 240	
	Epirubicin HCL, 2.0 mg/ml	> 240	Epirubicin HCL, 2.0 mg/ml	> 240	
	Etoposide (20.0 mg/ml)	> 240	Etoposide (20.0 mg/ml)	> 240	
	Fluorouracil (50.0 mg/ml)	> 240	Fluorouracil (50.0 mg/ml)	> 240	
	Gemcitabine, 38.0 mg/ml	> 240	Gemcitabine, 38.0 mg/ml	> 240	
	Ifosfamide, 50.0 mg/ml	> 240	Ifosfamide, 50.0 mg/ml	> 240	
	Irinotecan, 20.0 mg/ml	> 240	Irinotecan, 20.0 mg/ml	> 240	
	Methotrexate (25.0 mg/ml)	> 240	Methotrexate (25.0 mg/ml)	> 240	
	Methotrexate (25.0 mg/ml)	> 240	Methotrexate (25.0 mg/ml)	> 240	
	Mitomycin C (0.5 mg/ml)	> 240	Mitomycin C (0.5 mg/ml)	> 240	
	Mitoxantrone, 2.0 mg/ml	> 240	Mitoxantrone, 2.0 mg/ml	> 240	
	Oxaliplatin, 5.0 mg/ml	> 240	Oxaliplatin, 5.0 mg/ml	> 240	
	Paclitaxel (6.0 mg/ml)	> 240	Paclitaxel (6.0 mg/ml)	> 240	
	Thiotepa (10.0 mg/ml)	37.8	Thiotepa (10.0 mg/ml)	67.2	
	Vincristine Sulfate (1.0 mg/ml)	> 240	Vincristine Sulfate (1.0 mg/ml)	> 240	
	Oncovin (1.0 mg/ml)	> 240	Oncovin (1.0 mg/ml)	> 240	
	Vinorelbine, 10.0 mg/ml	> 240	Vinorelbine, 10.0 mg/ml	> 240	
	Fentanyl Citrate, 100.0 mcg/2ml	> 240	Fentanyl Citrate, 100.0 mcg/2ml	> 240	

Characteristics and Parameters	Subject Device	Predicate Device (K200581)	Discussion
Color	Fusion Colour	Blue	Different
Design	• Single Use • Non-sterile • Powder-Free • Ambidextrous	• Single Use • Non-sterile • Powder-Free • Ambidextrous	Similar
Sterility	Non-sterile	Non-sterile	Same
Freedom from holes	Meets ASTM D5151-19: AQL 1.5	Meets ASTM D5151-06(2015): AQL 1.5	Similar
Length	Meets ASTM D6319-19: XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm	Meets ASTM D6319-10(2015): ≥ 230 mm	Similar

Characteristics and Parameters	Subject Device	Predicate Device (K200581)	Discussion
Width	Meets ASTM D6319-19: XS: 60 - 80 mm S: 70 - 90 mm M: 85 - 105 mm L: 100 - 120 mm XL: 110 - 130 mm	Meets ASTM D6319-10(2015): XS: 60 - 80 mm S: 70 - 90 mm M: 85 - 105 mm L: 100 - 120 mm XL: 110 - 130 mm	Similar
Thickness	Meets ASTM D6319-19: Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm	Meets ASTM D6319-10(2015): Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm	Similar
Physical Properties	Meets ASTM D6319-19: Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Meets ASTM D6319-10(2015): Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Similar
Powder residual	Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Similar
In vitro Cytotoxicity ISO 10993-5	The neat extract was found to be cytotoxic	NA	Different
Dermal Sensitization ISO 10993-10	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer	Similar

Characteristics and Parameters	Subject Device	Predicate Device (K200581)	Discussion
Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Similar
Primary Skin Irritation ISO 10993-23	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device is not an irritant	Similar
Shelf-Life Expiry ASTM D7160-16	3 years	3 years	Identical

SUMMARY OF NON-CLINICAL TESTING:

Provided are the test methodology used to demonstrate whether the subject device met the acceptance criteria in each respective standard.

- Biodegradability is not a medical claim and therefore was not reviewed by FDA.
- **ASTM D6319-19** Standard Specification for Nitrile Examination Gloves for Medical Application
- **ASTM D5151-19** Standard Test Method for Detection of Holes in Medical Gloves
- **ASTM D6124-06** (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- **ASTM D6978-05** (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- **ISO 10993-5** Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- **ISO 10993-10** Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- **ISO 10993-11** Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **ISO 10993-23** Biological evaluation of medical devices - Part 23: Tests for irritation
- **ASTM D7160-16** Standard Practice for Determination of Expiration Dating for Medical Gloves

Physical Characteristics

<table>
<tr><th>Test Methodology/ Standards</th><th>Acceptance Criteria of the Standards</th><th>Result Summary</th></tr>
<tr><td>Dimensions

ASTM D6319-19
Standard Specification for Nitrile Examination Gloves for Medical Application</td><td><table><tr><th>Size</th><th>Length (mm)</th><th>Width (mm)</th></tr><tr><td>XS</td><td>Min 220</td><td>70 ± 10</td></tr><tr><td>S</td><td>Min 220</td><td>80 ± 10</td></tr><tr><td>M</td><td>Min 230</td><td>95 ± 10</td></tr><tr><td>L</td><td>Min 230</td><td>110 ± 10</td></tr><tr><td>XL</td><td>Min 230</td><td>120 ± 10</td></tr></table></td><td>Meets ASTM D6319-19 requirements for length, and width. Similar to predicate device.<table><tr><th>Size</th><th>Average Length (mm)</th><th>Average Width (mm)</th></tr><tr><td>XS</td><td>240</td><td>76</td></tr><tr><td>S</td><td>242</td><td>86</td></tr><tr><td>M</td><td>239</td><td>97</td></tr><tr><td>L</td><td>246</td><td>107</td></tr><tr><td>XL</td><td>245</td><td>114</td></tr></table></td></tr>
<tr><td>Dimensions

ASTM D6319-19
Standard Specification for Nitrile Examination Gloves for Medical Application</td><td>Thickness (mm)<table><tr><td>Palm</td><td>Minimum 0.05</td></tr><tr><td>Finger</td><td>Minimum 0.05</td></tr></table></td><td>Meets ASTM D6319-19 requirements for thickness. Similar to predicate device<table><tr><th>Size</th><th>Average Palm Thickness (mm)</th><th>Average Finger Thickness (mm)</th></tr><tr><td>XS</td><td>0.05</td><td>0.08</td></tr><tr><td>S</td><td>0.05</td><td>0.08</td></tr><tr><td>M</td><td>0.06</td><td>0.08</td></tr><tr><td>L</td><td>0.06</td><td>0.08</td></tr><tr><td>XL</td><td>0.06</td><td>0.08</td></tr></table></td></tr>
</table>

Physical Properties ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	**Parameter** / **Before Aging** / **After Aging** Tensile Strength: Min 14 MPa / Min 14 MPa Ultimate Elongation: Min 500% / Min 400%	Meets ASTM D6319-19 requirements for tensile strength and elongation at break before and after accelerated aging. Similar to predicate device. **<u>Before Age</u>** **Tensile Strength (MPa)** Average 35 **Elongation at Break (%)** Average 565 **<u>After Age</u>** **Tensile Strength (MPa)** Average 36 **Elongation at Break (%)** Average 469
Freedom from holes ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	AQL 2.5	Meets ASTM D6319-19 and ASTM D5151-19 requirements of AQL 2.5. Similar to predicate device. Inspection Level G1 AQL Level 1.5 Although pass at AQL 1.5 quality level, it complies with ASTM D6319-19 and ASTM D5151-19. requirements of AQL 2.5
Powder residual ASTM D6124-06(2017) Standard Test Method for Residual Powder on Medical Gloves ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	Powder Free; ≤ 2 mg per glove	Meets ASTM D6319-19 and ASTM D6124-06 (2017) requirements for Powder Free; ≤ 2 mg per glove. Similar to predicate device. Average 0.14 mg/glove

<table>
<tr>
<td>Chemotherapy Drugs Permeation

ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs</td>
<td>Under the conditions of the study, the permeation is acceptable.</td>
<td>
<table>
<tr><th>Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><td>5- Azacytidine, 25.0 mg/ml</td><td>> 240</td></tr>
<tr><td>Carboplatin, 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>12.1</td></tr>
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<tr><td>Dacarbazine (10.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Docetaxel, 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>Doxorubicin HCL (2.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Epirubicin HCL, 2.0 mg/ml</td><td>> 240</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td>> 240</td></tr>
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<tr><td>Paclitaxel (6.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Thiotepa (10.0 mg/ml)</td><td>37.8</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Oncovin (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Vinorelbine, 10.0 mg/ml</td><td>> 240</td></tr>
<tr><td>Fentanyl Citrate, 100.0 mcg/2ml</td><td>> 240</td></tr>
</table>

Under the conditions of the study, the permeation is acceptable. Similar to predicate devices. Performance level of drugs between subject device and predicate devices are comparable.
</td>
</tr>
</table>

Biocompatibility

Test Methodology/ Standards	Acceptance Criteria of the Standards	Result Summary
In Vitro Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the device is not cytotoxic	Under the conditions of the study, the device to be found have cytotoxic effect
Dermal Sensitization ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer.

Primary Skin Irritation ISO 10993-23:2021 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device is not an irritant.
Acute Systemic Toxicity ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Under the conditions of the study, the device does not pose a toxicity concern	Under the conditions of the study, there was no signs of toxicity.

CLINICAL PERFORMANCE DATA:

Not applicable. There was no clinical data required to support the subject device as the indication for use is equivalent to the predicate devices.

CONCLUSION:

The conclusion drawn from the non-clinical tests demonstrates that the subject device herein mentioned is as safe, effective, and performs as well as or better than the legally marketed predicate device (K200581).