October 26, 2022

PT. Sintong Unigolden Glove
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114
Aurora, Illinois 60504

Re: K223235
Trade/Device Name: Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: October 19, 2022
Received: October 19, 2022

Dear Manoj Zacharias:

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, 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)*
K223235

Device Name
Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)

Indications for Use *(Describe)*

Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. This is a single-use, powder-free, non-sterile device.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carboplatin	10 mg/ml (10,000 ppm)	> 240 Minutes
Carmustine	3.3 mg/ml (3,300 ppm)	15.9 Minutes
Cisplatin	1 mg/ml (1,000 ppm)	> 240 Minutes
Cyclophosphamide	20 mg/ml (20,000 ppm)	> 240 Minutes
Cytarabine HCl	100 mg/ml (100,000 ppm)	> 240 Minutes
Dacarbazine	10 mg/ml (10,000 ppm)	> 240 Minutes
Docetaxel	10 mg/ml (10,000 ppm)	> 240 Minutes
Doxorubicin HCl	2 mg/ml (2,000 ppm)	> 240 Minutes
Etoposide	20 mg/ml (20,000 ppm)	> 240 Minutes
Fluorouracil	50 mg/ml (50,000 ppm)	> 240 Minutes
Gemcitabine	38 mg/ml (38,000 ppm)	> 240 Minutes
Ifosfamide	50 mg/ml (50,000 ppm)	> 240 Minutes
Irinotecan	20 mg/ml (20,000 ppm)	> 240 Minutes
Mechlorethamine HCl	1 mg/ml (1,000 ppm)	> 240 Minutes
Melphalan	5 mg/ml (5,000 ppm)	> 240 Minutes
Methotrexate	25 mg/ml (25,000 ppm)	> 240 Minutes
Mitoxantrone	2 mg/ml (2,000 ppm)	> 240 Minutes
Paclitaxel	6 mg/ml (6,000 ppm)	> 240 Minutes
Thiotepa	10 mg/ml (10,000 ppm)	54.2 Minutes

Please note that the following drugs have low permeation times:
Carmustine 3.3 mg/ml 15.9 Minutes
Thiotepa 10 mg/ml 54.2 Minutes

Warning: Please do not use with Carmustine and Thiotepa.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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."

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

K223235

A. APPLICANT INFORMATION

510(K) Owner's Name	PT. Sintong Unigolden Glove
Address	Jl. Lintas Sumatera, Kel. Hessa Perlompongan, Kec. Air Batu, Kab. Asahan, Kota Kisaran, Sumatera Utara, Indonesia 21272
Phone	+62623533339
Fax	+62623533330
E-mail	sug.qualityassurance@gmail.com
Contact Person	Vivekanandan
Designation	Production Manager
Contact Number	+681253206449
Contact Email	vivekmp80@gmail.com
Date Submitted	13 October 2022

B. DEVICE IDENTIFICATION

Name of the device	Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)
Product proprietary or trade name	Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)
Common or usual name	Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)
Classification name	Patient Examination Glove, Specialty
Device Classification	Class-1
Product Code	LZA, LZC, OPJ
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Nitrile Patient Examination Gloves Blue Colored Tested For Use With Chemotherapy Drugs
510(k) Number	K213040
Regulatory Class	Class 1
Product code	LZA, LZC, OPJ

Reference Device	Non-Sterile Nitrile Powder Free Examination Gloves - Blue, Green and Black color
510(k) Number	K210388
Regulatory Class	Class 1
Product code	LZA

D. DESCRIPTION OF THE DEVICE:

Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) is a Class I patient examination gloves bearing the product codes LZA, LZC, OPJ (21CFR880.6250). They meet all the current specifications listed under the ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application and also complies with requirements for Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs as per ASTM D6978-05 (2019). They are made from Carboxylated Nitrile. These gloves are blue in color and are powder free. The product is non-sterile, textured, ambidextrous with beaded cuff and single use only.

Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) with sizes X-Small, Small, Medium, Large, X-Large and XX-Large are included in the submission.

E. INDICATION FOR USE OF THE DEVICE:

Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. This is a single-use, powder-free, non-sterile device.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carboplatin	10 mg/ml (10,000 ppm)	> 240 Minutes
Carmustine	3.3 mg/ml (3,300 ppm)	15.9 Minutes
Cisplatin	1 mg/ml (1,000 ppm)	> 240 Minutes
Cyclophosphamide	20 mg/ml (20,000 ppm)	> 240 Minutes
Cytarabine HCl	100 mg/ml (100,000 ppm)	> 240 Minutes
Dacarbazine	10 mg/ml (10,000 ppm)	> 240 Minutes
Docetaxel	10 mg/ml (10,000 ppm)	> 240 Minutes
Doxorubicin HCl	2 mg/ml (2,000 ppm)	> 240 Minutes
Etoposide	20 mg/ml (20,000 ppm)	> 240 Minutes
Fluorouracil	50 mg/ml (50,000 ppm)	> 240 Minutes
Gemcitabine	38 mg/ml (38,000 ppm)	> 240 Minutes
Ifosfamide	50 mg/ml (50,000 ppm)	> 240 Minutes
Irinotecan	20 mg/ml (20,000 ppm)	> 240 Minutes
Mechlorethamine HCl	1 mg/ml (1,000 ppm)	> 240 Minutes
Melphalan	5 mg/ml (5,000 ppm)	> 240 Minutes
Methotrexate	25 mg/ml (25,000 ppm)	> 240 Minutes
Mitoxantrone	2 mg/ml (2,000 ppm)	> 240 Minutes
Paclitaxel	6 mg/ml (6,000 ppm)	> 240 Minutes
Thiotepa	10 mg/ml (10,000 ppm)	54.2 Minutes

Please note that the following drugs have low permeation times:
Carmustine (3.3 mg/ml) 15.9 Minutes
Thiotepa (10 mg/ml) 54.2 Minutes
Warning: Do not use with Carmustine & Thiotepa

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	**K213040**	**K210388**	K223235	
Name of device	---	Nitrile Patient Examination Gloves Blue Colored Tested For Use With Chemotherapy Drugs	Non Sterile Nitrile Powder Free Examination Gloves – Blue, Green And Black color	Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs)	Similar to predicate device
Product Code	---	LZA, LZC, OPJ	LZA	LZA, LZC, OPJ	Similar to predicate device
Indication for use	---	The blue colored nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device. The Nitrile Patient Examination Gloves Blue Colored were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. This is a single-use, powder-free, non-sterile device.	Similar to predicate device
Regulation Number		21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	**K213040**	**K210388**	K223235	
Material		Powder-Free Nitrile	Carboxylated Butadiene Acrylonitrile as base material	Carboxylated Nitrile Rubber	Same as the reference device
Color	---	Blue	Blue, Green and Black	Blue	Same as predicate device
Size	---	X-Small, Small, Medium, Large, X-Large and XX-Large	Small, Medium, Large and X-Large	X-Small, Small, Medium, Large, X-Large and XX-Large	Same as predicate device
Single Use	---	Single Use	Single Use	Single Use	Same
Sterile/non sterile	---	non sterile	non sterile	non sterile	Same
Rx Only or OTC	---	Over the Counter	Over the Counter	Over the Counter	Same
Dimensions - Length	ASTM D6319-19	XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min)	240-246 mm (Medium)	XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min)	Same as predicate device
				Size / **Average value** X- Small / 270 Small / 273 Medium / 274 Large / 276 X-Large / 278 XX-Large / 276	
Dimensions - Width	ASTM D6319-19	XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm) XXL (≥120mm)	95-98 mm (Medium)	XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm) XXL (130±10mm)	Similar
				Size / **Average value** X-Small / 72 Small / 82 Medium / 97 Large / 103 X-Large / 112 XX-Large / 126	

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

<table>
<tr><th>CHARACTERISTICS</th><th>STANDARDS</th><th colspan="3">DEVICE PERFORMANCE</th><th>Comparison</th></tr>
<tr><td></td><td></td><td>PREDICATE</td><td>REFERENCE</td><td colspan="2">SUBJECT</td><td></td></tr>
<tr><td>510(K) Number</td><td>---</td><td>K213040</td><td>K210388</td><td colspan="2">K223235</td><td></td></tr>
<tr><td rowspan="8">Physical Properties-Tensile Strength</td><td rowspan="8">ASTM D6319-2019</td><td rowspan="8"><u>Before Ageing</u>
Tensile Strength
≥14MPa, min</td><td rowspan="8"><u>Before Ageing</u>
Tensile Strength
25.9-32.0 MPa
(Medium)</td><td colspan="2"><u>Before Ageing</u>
Tensile Strength
14MPa, min</td><td rowspan="8">Similar</td></tr>
<tr><td>Size</td><td>Average value</td></tr>
<tr><td>X-Small</td><td>17.7</td></tr>
<tr><td>Small</td><td>18.1</td></tr>
<tr><td>Medium</td><td>18.3</td></tr>
<tr><td>Large</td><td>18.4</td></tr>
<tr><td>X-Large</td><td>18.2</td></tr>
<tr><td>XX-Large</td><td>18.5</td></tr>
<tr><td rowspan="8"><u>After Ageing</u>
Tensile Strength
≥14MPa, min</td><td rowspan="8"><u>After Ageing</u>
Tensile Strength
25.4-34.0 MPa
(Medium)</td><td colspan="2"><u>After Ageing</u>
Tensile Strength
14MPa, min</td><td rowspan="8">Similar</td></tr>
<tr><td>Size</td><td>Average value</td></tr>
<tr><td>X-Small</td><td>16.8</td></tr>
<tr><td>Small</td><td>17.3</td></tr>
<tr><td>Medium</td><td>17.2</td></tr>
<tr><td>Large</td><td>17.6</td></tr>
<tr><td>X-Large</td><td>17.5</td></tr>
<tr><td>XX-Large</td><td>17.6</td></tr>
<tr><td rowspan="8">Physical Properties-Ultimate Elongation</td><td rowspan="8">ASTM D6319-2019</td><td rowspan="8"><u>Before Ageing</u>
Ultimate Elongation
500% min</td><td rowspan="8"><u>Before Ageing</u>
Ultimate Elongation
500-540 %
(Medium)</td><td colspan="2"><u>Before Ageing</u>
Ultimate Elongation
500% min</td><td rowspan="8">Same as predicate device</td></tr>
<tr><td>Size</td><td>Average value</td></tr>
<tr><td>X-Small</td><td>637</td></tr>
<tr><td>Small</td><td>634</td></tr>
<tr><td>Medium</td><td>647</td></tr>
<tr><td>Large</td><td>630</td></tr>
<tr><td>X-Large</td><td>644</td></tr>
<tr><td>XX-Large</td><td>644</td></tr>
<tr><td rowspan="8"><u>After Ageing</u>
Ultimate Elongation
400% min</td><td rowspan="8"><u>After Ageing</u>
Ultimate Elongation
480-520 %
(Medium)</td><td colspan="2"><u>After Ageing</u>
Ultimate Elongation
400% min</td><td rowspan="8">Same as predicate device</td></tr>
<tr><td>Size</td><td>Average value</td></tr>
<tr><td>X-Small</td><td>532</td></tr>
<tr><td>Small</td><td>539</td></tr>
<tr><td>Medium</td><td>542</td></tr>
<tr><td>Large</td><td>536</td></tr>
<tr><td>X-Large</td><td>529</td></tr>
<tr><td>XX-Large</td><td>533</td></tr>
</table>

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92(C)

<table>
<tr><th>CHARACTERISTICS</th><th>STANDARDS</th><th colspan="3">DEVICE PERFORMANCE</th><th>Comparison</th></tr>
<tr><td></td><td></td><td>PREDICATE</td><td>REFERENCE</td><td colspan="2">SUBJECT</td><td></td></tr>
<tr><td>510(K) Number</td><td>---</td><td>K213040</td><td>K210388</td><td colspan="2">K223235</td><td></td></tr>
<tr><td>Thickness</td><td>ASTM D6319-19</td><td>Palm
0.05mm min

Finger
0.11 mm min</td><td>Palm
0.06-0.06 mm
(Medium)

Finger
0.09-0.10 mm
(Medium)</td><td colspan="2">Palm 0.05 mm min;
Finger 0.05 mm min
Size | Palm (Avg value) | Finger (Avg value)
X-Small | 0.12 | 0.14
Small | 0.12 | 0.14
Medium | 0.12 | 0.14
Large | 0.12 | 0.14
X-Large | 0.12 | 0.14
XX-Large | 0.12 | 0.14</td><td>Similar</td></tr>
<tr><td>Powder Free Residue</td><td>ASTM D6319-19</td><td><2mg per glove</td><td>0.70 mg/glove
(Medium)</td><td colspan="2">≤2 mg/glove
Size | Average value
X-Small | 0.21
Small | 0.18
Medium | 0.18
Large | 0.19
X-Large | 0.21
XX-Large | 0.20</td><td>Similar</td></tr>
<tr><td>Freedom from holes</td><td>ASTM D5151-2019</td><td>Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 1.5</td><td>Inspection Level G-1; AQL=2.5</td><td colspan="2">Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5</td><td>Same as reference device</td></tr>
<tr><td rowspan="9">Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time</td><td rowspan="9">ASTM D6978-05 (2019)</td><td>Bleomycin Sulfate 15 mg/ml >240 min.</td><td>NA</td><td colspan="2">Not tested</td><td>Optional*</td></tr>
<tr><td>Carboplatin 10 mg/ml >240 min.</td><td>NA</td><td colspan="2">Carboplatin 10 mg/ml (10,000 ppm) > 240 Minutes</td><td>Same</td></tr>
<tr><td>Carmustine (BCNU) 3.3 mg/ml 17.2 min.</td><td>NA</td><td colspan="2">Carmustine 3.3 mg/ml (3,300 ppm) 15.9 Minutes</td><td>Similar</td></tr>
<tr><td>Cisplatin 1.0 mg/ml >240 min.</td><td>NA</td><td colspan="2">Cisplatin 1 mg/ml (1,000 ppm) > 240 Minutes</td><td>Same</td></tr>
<tr><td>Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.</td><td>NA</td><td colspan="2">Cyclophosphamide 20 mg/ml (20,000 ppm) ＞ 240 Minutes</td><td>Same</td></tr>
<tr><td>Cytarabine HCl 100 mg/ml >240 min.</td><td>NA</td><td colspan="2">Cytarabine HCl 100 mg/ml (100,000 ppm) ＞240 Minutes</td><td>Same</td></tr>
<tr><td>Dacarbazine (DTIC) 10.0 mg/ml >240 min.</td><td>NA</td><td colspan="2">Dacarbazine 10 mg/ml (10,000 ppm) ＞ 240 Minutes</td><td>Same</td></tr>
<tr><td>Daunorubicin 5.0 mg/ml >240 min.</td><td>NA</td><td colspan="2">Not tested</td><td>Optional*</td></tr>
<tr><td>Docetaxel 10.0 mg/ml >240 min</td><td>NA</td><td colspan="2">Docetaxel 10 mg/ml (10,000 ppm) ＞240 Minutes</td><td>Same</td></tr>
</table>

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	**K213040**	**K210388**	K223235	
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	ASTM D6978-05 (2019)	Doxorubicin HCl 2.0 mg/ml >240 min.	NA	Doxorubicin HCl 2 mg/ml (2,000 ppm) > 240 Minutes	Same
		Etoposide (Toposar) 20.0 mg/ml >240 min.	NA	Etoposide 20 mg/ml (20,000 ppm) > 240 Minutes	Same
		Fluorouracil 50.0 mg/ml >240 min.	NA	Fluorouracil 50 mg/ml (50,000 ppm) > 240 Minutes	Same
		Gemcitabine 38 mg/ml >240 min.	NA	Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes	Same
		Idarubicin 1 mg/ml >240 min.	NA	Not tested	Optional*
		Ifosfamide 50.0 mg/ml >240 min.	NA	Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes	Same
		Irinotecan 20.0 mg/ml >240 min.	NA	Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes	Same
		Mechlorethamine HCl 1.0 mg/ml >240 min.	NA	Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes	Same
		Melphalan 5 mg/ml >240 min.	NA	Melphalan 5 mg/ml (5,000 ppm) >240 Minutes	Same
		Methotrexate 25 mg/ml >240 min.	NA	Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes	Same
		Mitromycin C. 0.5 mg/ml >240 min.	NA	Not tested	Optional*
		Mitoxantrone 2.0 mg/ml >240 min.	NA	Mitoxantrone 2 mg/ml (2,000ppm) > 240 Minutes	Same
		Paclitaxel (Taxol) 6.0 mg/ml >240 min.	NA	Paclitaxel 6 mg/ml (6,000 ppm) > 240 Minutes	Same
		Thiotepa 10.0 mg/ml 13.9 min.	NA	Thiotepa 10 mg/ml (10,000 ppm) 54.2 Minutes	Similar
		Vincristine Sulfate 1.0 mg/ml >240 min.	NA	Not tested	Optional*
Contact Durations	---	Limited <24 hours	---	Limited <24 hours	Same
Biocompatibility	Primary Skin Irritation- ISO 10993-23: First Edition 2021-01	Not a skin irritant	Non-irritant (Response Category is Negligible)	Under the condition of study not an irritant	Same
	Dermal Sensitization- ISO 10993-10: Fourth Edition 2021-11	Not a skin sensitizer	Non-sensitizer (No sensitization)	Under the conditions of the study not a sensitizer	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			Comparison
		PREDICATE	REFERENCE	SUBJECT	
510(K) Number	---	**K213040**	**K210388**	K223235	
Biocompatibility	In vitro cytotoxicity- ISO 10993-5: Third Edition 2009-06-01	At the neat extraction, the test article is considered cytotoxic	---	Under the conditions of the study, non-cytotoxic	Different** .
	Acute Systemic Toxicity- ISO 10993-11: Third Edition 2017-09	The acute systemic toxicity results demonstrate the device will not cause a systemic effect.	No toxic effects	Under the conditions of the study, the test item did not produce any adverse effect	Same

* Predicate device perform additional Chemotherapy drug test.

** The difference does not raise any issue regarding the safety or effectiveness of the glove since the subject glove is non-cytotoxic.

There are no significant differences between the products other than In vitro cytotoxicity study and are identical in terms of intended use, materials, design and manufacturing methods. The devices meet the ASTM standard D6319-19 and D6978-05 (2019).

G. NON-CLINICAL TESTING SUMMARY PERFORMANCE DATA

BENCH TEST DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the length of the gloves	X-Small : 220 mm min Small : 220 mm min Medium : 230 mm min Large : 230 mm min X-Large : 230 mm min XX-Large : 230 mm min	X-Small : 270 mm Small : 273 mm Medium : 274 mm Large : 276 mm X-Large : 278 mm XX-Large : 276 mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the width of the gloves	X-Small : 70+/-10 mm Small : 80+/-10 mm Medium : 95+/-10 mm Large : 110+/-10 mm X-Large : 120+/-10 mm X-Large : 130+/-10 mm	X-Small : 72 mm Small : 82 mm Medium : 97 mm Large : 103 mm X-Large : 112 mm XX-Large : 126 mm

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92(C)

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the thickness of the gloves	Palm: 0.05 mm min for all sizes Finger: 0.05 mm min for all sizes	**Size**	**Palm**	**Finger**
			X-Small	0.12 mm	0.14 mm
			Small	0.12 mm	0.14 mm
			Medium	0.12 mm	0.14 mm
			Large	0.12 mm	0.14 mm
			X-Large	0.12 mm	0.14 mm
			XX-Large	0.12 mm	0.14 mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 14MPa min for all sizes **After Ageing** Tensile Strength 14MPa min for all sizes	**Size**	**Before ageing**	**After ageing**
			X-Small	17.7 MPa	16.8 MPa
			Small	18.1 MPa	17.3 MPa
			Medium	18.3 MPa	17.2 MPa
			Large	18.4 MPa	17.6 MPa
			X-Large	18.2 MPa	17.5 MPa
			XX-Large	18.5 MPa	17.6 MPa
	To determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% min for all sizes **After Ageing** Ultimate Elongation 400% min for all sizes	**Size**	**Before ageing**	**After ageing**
			X-Small	637%	532%
			Small	634%	539%
			Medium	647%	542%
			Large	630%	536%
			X-Large	644%	529%
			XX-Large	644%	533%
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5		
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤ 2 mg/glove	X-Small : 0.21 mg/glove Small : 0.18 mg/glove Medium : 0.18 mg/glove Large : 0.19 mg/glove X-Large : 0.21 mg/glove XX-Large : 0.20 mg/glove		

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	To determine the breakthrough detection time of chemotherapy drugs	Carboplatin 10 mg/ml (10,000 ppm) > 240 Minutes	Carboplatin 10 mg/ml (10,000 ppm) > 240 Minutes
		Cisplatin 1 mg/ml (1,000 ppm) > 240 Minutes	Cisplatin 1 mg/ml (1,000 ppm) > 240 Minutes
		Cyclophosphamide 20 mg/ml (20,000 ppm) ＞ 240 Minutes	Cyclophosphamide 20 mg/ml (20,000 ppm) ＞ 240 Minutes
		Cytarabine HCl 100 mg/ml (100,000 ppm) ＞240 Minutes	Cytarabine HCl 100 mg/ml (100,000 ppm) ＞240 Minutes
		Dacarbazine 10 mg/ml (10,000 ppm) ＞ 240 Minutes	Dacarbazine 10 mg/ml (10,000 ppm) ＞ 240 Minutes
		Docetaxel 10 mg/ml (10,000 ppm) ＞240 Minutes	Docetaxel 10 mg/ml (10,000 ppm) ＞240 Minutes

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	To determine the breakthrough detection time of chemotherapy drugs	Doxorubicin HCl 2 mg/ml (2,000 ppm) > 240 Minutes	Doxorubicin HCl 2 mg/ml (2,000 ppm) > 240 Minutes
		Etoposide 20 mg/ml (20,000 ppm) > 240 Minutes	Etoposide 20 mg/ml (20,000 ppm) > 240 Minutes
		Fluorouracil 50 mg/ml (50,000 ppm) > 240 Minutes	Fluorouracil 50 mg/ml (50,000 ppm) > 240 Minutes
		Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes	Gemcitabine 38 mg/ml (38,000 ppm) >240 Minutes
		Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes	Ifosfamide 50 mg/ml (50,000 ppm) >240 Minutes
		Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes	Irinotecan 20 mg/ml (20,000 ppm) >240 Minutes
		Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes	Mechlorethamine HCl 1 mg/ml (1,000 ppm) >240 Minutes
		Melphalan 5 mg/ml (5,000 ppm) >240 Minutes	Melphalan 5 mg/ml (5,000 ppm) >240 Minutes
		Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes	Methotrexate 25 mg/ml (25,000 ppm) >240 Minutes
		Mitoxantrone 2 mg/ml (2,000ppm) > 240 Minutes	Mitoxantrone 2 mg/ml (2,000ppm) > 240 Minutes
		Paclitaxel 6 mg/ml (6,000 ppm) > 240 Minutes	Paclitaxel 6 mg/ml (6,000 ppm) > 240 Minutes

BIOCOMPATIBILITY DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ISO 10993-23 First edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.	To evaluate the test item, for skin irritation test in New Zealand White rabbits.	Under the condition of study not an irritant	Under the condition of study, not an irritant
10993-10 Fourth edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.	To evaluate the test item, for the skin sensitization in Guinea pigs by maximization test.	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer
ISO 10993-5 Third edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.	To evaluate the test item, for its ability to induce cytotoxicity using L-929 mouse fibroblast cells by Elution Method.	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, non-cytotoxic
ISO 10993-11 Third edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.	To evaluate the test item, for acute systemic toxicity in Sprague Dawley Rats.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the conditions of the study, the test item did not produce any adverse effect

The performance test data of the non-clinical tests that support a determination of safety and equivalence is the same as mentioned above (ASTM Requirements).

The performance test data of the non-clinical tests meet following standards:

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 10993-23 First Edition 2021-01 Biological Evaluation of Medical Devices - Part 23, Tests for Irritation.

ISO 10993-10 Fourth Edition 2021-11 Biological Evaluation of Medical Devices - Part 10, Tests for Skin Sensitization.

ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.

ISO 10993-11 Third Edition 2017-09 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.

H. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves.

I. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(K) submission, Nitrile Examination Gloves Powder Free (Tested for use with Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed predicate device **K213040.**