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

August 25, 2017

Yty Industry (manjung) Sdn Bhd
Punitha Samy
Deputy Manager-DC/RA
Lot 1422-1424, Batu 10 Lekir
Sitiawan, 32020 My

Re: K171104
Trade/Device Name: Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs (Blue) and Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs (Cobalt Blue)

Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC, LZA
Dated: July 19, 2017
Received: August 3, 2017

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
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)*

K171104

Device Name

Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - 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)	15.0 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)	30.1minutes
Vincristine Sulfate, 1.0 mg/ml	> 240 minutes

The following chemotherapy drugs and concentration have extremely low permeation time.
Carmustine (3.3 mg/ml): 15.0 minutes ThioTEPA (10.0 mg/ml): 30.1 minutes

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)*

K171104

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)	2.4 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)	1.9 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): 2.4 minutes ThioTEPA (10.0 mg/ml): 1.9 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.

510 (K) SUMMARY

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 August 24, 2017

3.0 Name of Device

Trade Name: Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - Blue
Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - 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	Brightway Brand Nitrile Examination Gloves, Powder Free, [Sterling/Grey] Tested For Use With Chemotherapy Drugs
Predicate 510(K) number:	K161215
Device Classification:	I
Product Code:	LZC

5.0 Description of The Device

Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs – Blue and Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - 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	Blue	Cobalt Blue
		Average Breakthrough Detection Time (minutes)	
Carboplatin	10mg/ml	> 240	> 240
*Carmustine	3.3mg/ml	15.0	2.4
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	30.1	1.9
Vincristine Sulfate	1.0mg/ml	> 240	> 240
Warning Statement		*WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 15.0 minutes and ThioTepa: 30.1 minutes. NOT TO BE USED WITH CARMUSTINE OR THIOTEPA	* WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 2.4 minutes and ThioTepa: 1.9 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 Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs – Blue and Non-Sterile, Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs - 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

Characteristic		Standards	Device Performance		
			Predicate	Blue	Cobalt Blue
510(K) Number			K161215	K171104	K171104
Dimension		ASTM D6319-10	Min 240mm	Min 240mm	Min 240mm
Physical Properties		ASTM D6319-10	Meets	Meets	Meets
Thickness	Finger Palm Cuff	ASTM D6319-10	0.03 – 0.05mm 1.5 – 0.08mm 1.6 – 0.09mm	0.03mm min 0.05mm min 0.05mm min	0.03mm min 0.05mm min 0.05mm min
Powder-free		ASTM D6124-06 (≤ 2mg/glove)	Meets	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	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	Under the condition of the study the device is non-sensitizer

Table 2

Characteristic	Tested according to ASTM D6978-05	Device Performance		
		Predicate- K161215	Blue	Cobalt Blue
		Average Breakthrough Detection Time (minutes)		
	Concentration	Predicate	Current	Current
Carboplatin	10mg/ml	-	> 240	> 240
*Carmustine	3.3mg/ml	10.1	15.0	2.4
Cisplatin	1.0mg/ml	> 240	> 240	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240	> 240	> 240
Dacarbazine (DTIC)	10.0mg/ml	> 240	> 240	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240	> 240	> 240
Etoposide (Toposar)	20.0mg/ml	> 240	> 240	> 240
Fluorouracil	50.0mg/ml	> 240	> 240	> 240
Ifosfamide (Ifex)	50.0mg/ml	> 240	> 240	> 240
Methotrexate	25mg/ml	-	> 240	> 240
Mitomycin C	0.5mg/ml	-	> 240	> 240
Mitoxantrone	2 mg/ml	> 240	> 240	> 240
Paclitaxel (Taxol)	6.0mg/ml	> 240	> 240	> 240
Thiotepa	10.0mg/ml	30.2	30.1	1.9
Vincristine Sulfate	1.0mg/ml	> 240	> 240	> 240
Warning Statement		*WARNING: Do Not Use with Carmustine and Thiotepa. Carmustine and Thiotepa has extremely low permeation time of less than 30 minutes respectively	*WARNING: Please note that the following drugs have extremely low permeation times: Carmustine: 15.0 minutes and ThioTepa: 30.1 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

Table 3

Characteristics	**Predicate** K161215	**Subject Device** **Blue**	**Subject Device** **Cobalt Blue**	**Comparison**
Water tightness (1000ml)	Passes	Passes	Passes	Same
Color	Sterling/Grey	Blue	Cobalt Blue	Different
Material	Nitrile	Nitrile	Nitrile	Same
Size	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Texture	Finger Textured	Finger Textured	Finger Textured	Same
Single Use	Single Use	Single Use	Single Use	Same
Expiration claim	No Expiration Date Claimed	5 years	5 years	Different
Bio-compatibility	Passes Not primary skin irritant under the conditions of the study.	Passes Under the condition of the study the device is non-irritant	Passes Under the condition of the study the device is non-irritant	Same
	Passes Not a contact sensitizer under the conditions of the study.	Passes Under the condition of the study the device in non-sensitizer	Passes Under the condition of the study the device in non-sensitizer	Same

Indications for Use	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.	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.	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.	Same
	Tested Chemotherapy Drug And Concentration / Average Break through Detection Time	Average Break through Detection Time	Tested Chemotherapy Drug And Concentration / Average Break through Detection Time	
	Carmustine (3.3 mg/ml) 5.4 min Cisplatin (BCNU), 1.0 mg/ml >240 min Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min Dacarbazine (DTIC), 10.0 mg/ml >240 min Doxorubicin Hydrochloride, 2.0 mg/ml >240 min Etoposide (Toposar), 20.0 mg/ml >240 min Fluorouracil, 50.0 mg/ml >240 min Ifosfamide , 50.0 mg/ml >240 min Methotrexate, 25 mg/ml - Mitomycin C, 0.5 mg/ml - Mitoxantrone, 2 mg/ml >240 min Paclitaxel (Taxol), 6.0 mg/ml >240 min ThioTEPA (10.0 mg/ml) 40.4 min Vincristine Sulfate, 1.0 mg/ml >240 min	Carboplatin, 10 mg/ml >240 min Carmustine (3.3 mg/ml) 15.0 min Cisplatin (BCNU), 1.0 mg/ml >240 min Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min Dacarbazine (DTIC), 10.0 mg/ml >240 min Doxorubicin Hydrochloride, 2.0 mg/ml >240 min Etoposide (Toposar), 20.0 mg/ml >240 min Fluorouracil, 50.0 mg/ml >240 min Ifosfamide , 50.0 mg/ml >240 min Methotrexate, 25 mg/ml >240 min Mitomycin C, 0.5 mg/ml >240 min Mitoxantrone, 2 mg/ml >240 min Paclitaxel (Taxol), 6.0 mg/ml >240 min ThioTEPA (10.0 mg/ml) 30.1 min Vincristine Sulfate, 1.0 mg/ml >240 min	Carboplatin, 10mg/ml >240 min Carmustine (3.3 mg/ml) 2.4 min Cisplatin (BCNU), 1.0 mg/ml >240 min Cyclophosphamide (Cytoxan), 20.0 mg/ml >240 min Dacarbazine (DTIC), 10.0 mg/ml >240 min Doxorubicin Hydrochloride, 2.0 mg/ml >240 min Etoposide (Toposar), 20.0 mg/ml >240 min Fluorouracil, 50.0 mg/ml >240 min Ifosfamide , 50.0 mg/ml >240 min Methotrexate, 25 mg/ml >240 min Mitomycin C, 0.5 mg/ml >240 min Mitoxantrone, 2 mg/ml >240 min Paclitaxel (Taxol), 6.0 mg/ml >240 min ThioTEPA (10.0 mg/ml) 1.9 min Vincristine Sulfate, 1.0 mg/ml >240 min	Similar
	Tested for use with Chemotherapy Drugs. Carmustine has extremely low permeation time of less than 30 minutes	The following chemotherapy drugs and concentration have extremely low permeation time. Carmustine (3.3 mg/ml): 15.0 min ThioTEPA (10.0 mg/ml): 30.1 min	The following chemotherapy drugs and concentration have extremely low permeation time. Carmustine (3.3 mg/ml): 2.4 min ThioTEPA (10.0 mg/ml): 1.9 min	Same

8.0 Conclusion

The subject devices are as safe, as effective, and perform as well or better than the legally marketed predicate device K161215 (Nitrile Examination Gloves, Powder Free, [Sterling/Grey] Tested For Use With Chemotherapy Drugs).