DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 2, 2016

Maxter Glove Manufacturing SDN. BHD.
Yap Peak Geeh
QA & Regulatory Affairs Manager
Lot 6070, Jalan Haji Abdul Manan,
6th Miles Off Jalan Meru.
Klang, Selangor
41050 MALAYSIA

Re: K151390
Trade/Device Name: Powder Free Nitrile Examination Gloves Tested For Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC, LZA
Dated: March 25, 2016
Received: March 30, 2016

Dear Yap Geeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
Director
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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)*
K151390

Device Name
Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*
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.
In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTMD6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
Cisplatin, 1.0mg/ml	>240
Cyclophosphamide (Cytoxan), 20mg/ml	>240
Carmustine (BCNU), 3.3mg/ml	1.0
Dacarbazine (DTIC), 10.0mg/ml	>240
Doxorubicin Hydrochloride, 2.0mg/ml	>240
Etoposide (Toposar), 20.0mg/ml	>240
Fluorouracil, 50.0mg/ml	>240
Paclitaxel (Taxol), 6.0mg/ml	>240
Thiotepa, 10.0mg/ml	31.3
Methotrexate ,25mg/ml	>240
Mitomycin C, 0.5mg/ml	>240
Vincristine Sulfate, 1.0mg/ml	>240
Ifosfamide, 50.0mg/ml	>240

Please note that the following drugs have low permeation time of less than 240 minutes:
Carmustine (BCNU), 3.3mg/ml: 1.0 minute
Thiotepa, 10.0mg/ml: 31.3 minutes

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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1.0 Submitter:

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Phone No. : 6-03-33929888
Fax No. : 60-03-33923328
Date of Summary Prepared: 8th March 2016

2.0 Name of the device:

Powder Free Nitrile Examination Gloves Tested for use with Chemotherapy Drugs
Common Name : Exam Gloves
Classification Name: Patient Examination Gloves Speciality (21 CFR 880.6250 Product Code LZC, LZA)

3.0 Identification Of The Legally Marketed Devices that equivalency is claimed:

	Predicate
Manufacturer	WRP Asia Pacific Sdn Bhd
Device Name	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs
510(k) Number	K141982
Regulation Number	21 CFR 880.6250
Regulatory Name	Patient Examination Glove
Regulatory Class	I

4.0 Description of the Device:

These patient examination gloves are formulated using nitrile, non-sterile, powder free, meet all the requirements of ASTM D6319 and tested for use with chemotherapy drugs.

5.0 Intended Use of the Device:

A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands and finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTMD6978-05.

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6.0 Summary of the Technological Characteristics of the Device:

Below is the summary of the technological characteristics of the Powder Free Nitrile Examination Gloves compare to ASTM D6319 or equivalent standards.

Chemotherapy claim is similar to Predicate, which has a glove thickness below 0.1Omm and is shorter than 270mm but complaint with the ASTM standards.

Table 1

Characteristics	Standards	Device Performance	
		Predicate	Current
Manufacturer		WRP Asia Pacific Sdn Bhd	Maxter Gloves Manufacturing Sdn Bhd
510 (K) Number		K141982	K151390
Dimensions	ASTM D6319-10	Min240mm	Min270mm
Physical Properties	ASTM D6319-10	Meet	Meet
Thickness- Finger	ASTM D6319-10	0.07-0.lOmm	Min0.10mm
-palm		0.07-0.09mm	MinO.lOmm
Freedom From Holes	ASTM D6319-10 and ASTM D5151	Pass	Pass
Powder Free Residue	ASTM D6319-10 and ASTM D6124	Meet	Meet
Resistance to Permeation by Chemotherapy Drugs:	ASTM D6978-05		
Test Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time (min)	
Cisplatin	l.Omg/ml	>240 minutes	>240 minutes
Cyclophosphamide (Cytoxan)	20mg/ml	>240 minutes	>240 minutes
Carmustine (BCNU)	3.3mg/ml	15.0	1.0 minute
Dacarbazine {DTIC)	lO.Omg/ml	>240 minutes	>240 minutes
I toposide (Toposar)	20.0mg/ml	>240 minutes	>240 minutes
I oxorubicin I ydrochloride	2.0mg/ml	>240 minutes	>240 minutes

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Fluorouracil	50.0mg/ml	>240 minutes	>240 minutes
Paclitaxel (Taxol)	6.0mg/ml	>240 minutes	>240 minutes
Thiotepa	IO.Omg/ml	2.0 minutes	31.3 minutes
Methotrexate	25mg/ml	-	>240 minutes
Mitomycin C	0.5mg/ml	-	>240 minutes
Vincristine Sulfate	1.Omg/ml	>240 minutes	>240 minutes
Ifosfamide	50.0 mg/ml	>240 minutes	>240 minutes
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 low permeation time of less than 240minutes: Carmustine (BCNU): 1.0 Minute and Thiotepa : 31.3 Minutes
Biocompatibility	Primary Skin Irritation-ISO 10993	Pass	Pass
	Dermal Sensitization-ISO 10993	Pass	Pass
Intended Use	-	A 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.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands and finger to prevent contamination between patient and examiner.In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTMD6978-05.
Material	ASTM D6319-10	Nitrile	Nitrile
Texture	-	Finger Textured	Finger Textured

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Size	Medical Glove Guidance Manual-Labeling	Extra Small	Extra Small
		Small	Small
		Medium	Medium
		Large	Large
		Extra Lar_ge	Extra Large
Single Use	Medical Glove Guidance Manual-Labeling	Single use	Single use

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

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

The device and the predicate share the same intended use, same material, same specifications for thickness and length, similar permeation rates for chemotherapy

Drugs, similar labeling according to the glove guidance, and same compliance with standards for physical properties, powder free, biocompatibility and watertightness.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable- Clinical data is not needed for gloves or for most devices cleared by the 51O(K) process.

9.0 Conclusion

Based on intended uses, technological characteristics and non-clinical performance data, the Powder Free Nitrile Examination Gloves Tested for Use With Chemotherapy Drugs is substantially equivalent to the predicate device K141982.