May 2, 2018

Maxter Glove Manufacturing Sdn Bhd
Yap Peak Geeh
QA & Regulatory Affairs Manager
Lot 6070, Jalan Haji Abdul Manah
6th Miles off Jalan Meru
41050 Klang, Selangor
Malaysia

Re: K172864
Trade/Device Name: Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: March 30, 2018
Received: April 6, 2018

Dear Yap Peak 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172864

Device Name
Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder free nitrile 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 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
Carmustine (BCNU). 3.3mg/ml (3,300ppm)	8.3
Cisplatin. 1.0 mg/ml (1,000ppm)	>240
Cyclophosphamide (Cytoxan). 20mg/ml (20,000ppm)	>240
Cytarabine 100mg/ml (100,000ppm)	>240
Dacarbazine (DTIC), 10.0mg/ml (10,000ppm)	>240
Doxorubicin Hydrochloride. 2.0mg/ml (2,000ppm)	>240
Etoposide (Toposar), 20.0mg/ml (20,000ppm)	>240
Fluorouracil 50.0mg/ml (50,000ppm)	>240
Ifosfamide. 50.Omg/ml (50,000ppm)	>240
Methotrexate 25mg/ml (25,000ppm)	>240
Mitomycin C. 0.5mg/ml (500ppm)	>240
Mitoxantrone 2.0mg/ml (2,000ppm)	>240
Paclitaxel (Taxol). 6.0mg/ml (6,000ppm)	>240
Thiotepa. 10.0mg/ml (10,000ppm)	38.0
Vincristine Sulfate 1.0mg/ml (1,000ppm)	>240

Please note that the following drugs have low permeation time of less than 240minutes:

Carmustine (BCNU), 3.3mg/ml: 8.3 Minutes
Thiotepa. 10.0mg/ml: 38.0 Minutes

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

[ ] Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Date Prepared: 30th April 2018

1.0 Submitter:

Name	:	Maxter Glove Manufacturing Sdn Bhd
Address	:	Lot 6070 Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang, Selangor, Malaysia.
Phone No.	:	603-33929888
Fax No.	:	603-33923328

2.0 Name of the device:

Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

Common Name	:	Patient Examination Gloves
Brand Name	:	Maxter
Classification Name:		Polymer Patient Examination Glove (21 CFR 880.6250 Product Code LZA) Patient Examination Gloves Specialty (21 CFR 880.6250 Product Code LZC)

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

	Predicate
Manufacturer	Kossan International Sdn Bhd
Device Name	Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile. Tested for Use with Chemotherapy Drugs
510(k) Number	K151750
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 Indications for Use statement for the subject device:

A Non-Sterile Powder Free Blue Nitrile Examination Glove Tested for Use with Chemotherapy Drugs 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.

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
Carmustine (BCNU). 3.3mg/ml (3,300ppm)	8.3
Cisplatin. 1.0 mg/ml (1,000ppm)	>240
Cyclophosphamide (Cytoxan). 20mg/ml (20,000ppm)	>240
Cytarabine 100mg/ml (100,000ppm)	>240
Dacarbazine (DTIC), 10.0mg/ml (10,000ppm)	>240
Doxorubicin Hydrochloride. 2.0mg/ml (2,000ppm)	>240
Etoposide (Toposar), 20.0mg/ml (20,000ppm)	>240
Fluorouracil 50.0 mg/ml (50,000ppm)	>240
Ifosfamide 50.0 mg/ml (50,000ppm)	>240
Methotrexate 25mg/ml (25,000ppm)	>240
Mitomycin C. 0.5mg/ml (500ppm)	>240
Mitoxantrone 2.0mg/ml (2,000ppm)	>240
Paclitaxel (Taxol) 6.0mg/ml (6,000ppm)	>240
Thiotepa 10.0mg/ml (10,000ppm)	38
Vincristine Sulfate 1.0mg/ml (1,000ppm)	>240

Please note that the following drugs have low permeation time of less than 240minutes:
Carmustine (BCNU), 3.3mg/ml: 8.3 Minutes
Thiotepa. 10.0mg/ml: 38.0 Minutes

6.0 Summary of the Technological Characteristics Comparison:

Below is the summary of the technological characteristics of the Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs compare to ASTM D6319 or equivalent standards. Chemotherapy claim is similar to predicate device, which has a glove thickness of minimum 0.05mm and is shorter than 270mm but in compliance with the ASTM standards.

Table 1

Characteristics	**Standards**	**Device Performance**	
		Predicate	**Current**
Manufacturer		**Kossan International Sdn Bhd**	**Maxter Gloves Manufacturing Sdn Bhd**
510 (K) Number		K151750	K172864
Dimensions	ASTM D6319-10	≥ 230mm	≥ 230mm
Physical Properties	ASTM D6319-10	Meet	Meet

Thickness- Finger	ASTM D6319-10	≥ 0.05mm	≥ 0.05mm
-palm		≥ 0.05mm	≥ 0.05mm
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)**	
Carmustine (BCNU)	3.3mg/ml	10.1	8.3
Cisplatin	1.0mg/ml	>240	>240
Cyclophosphamide (Cytoxan)	20mg/ml	>240	>240
Cytarabine	100mg/ml	>240	>240
Dacarbazine (DTIC)	10.0mg/ml	>240	>240
Doxorubicin Hydrochloride	2.0mg/ml	>240	>240
Etoposide (Toposar)	20.0mg/ml	>240	>240
Ifosfamide	50.0 mg/ml	>240	>240
Methotrexate	25mg/ml	>240	>240
Mitomycin C.	0.5mg/ml	>240	>240
Mitoxantrone	2.0mg/ml	>240	>240
Paclitaxel (Taxol)	6.0mg/ml	>240	>240
Thiotepa	10.0mg/ml	30.2	38.0
Vincristine Sulfate	1.0mg/ml	>240	>240
Warning Statement		Warning: Please note that the following drugs have extremely low permeation times: Carmustine(BCNU): 10.1 minutes and Thiotepa: 30.2 minutes	Warning : Please note that the following drugs have low permeation time of less than 240 minutes: Carmustine (BCNU): 8.3 minutes and Thiotepa: 38.0 minutes. Do not use with Carmustine or Thiotepa.
Biocompatibility	Primary Skin Irritation-ISO 10993	Under the conditions of the study, this is a non-irritant.	Under the conditions of the study, this is a non-irritant.

	Dermal Sensitization-ISO 10993	Under the conditions of the study, this is a non-sensitizer.	Under the conditions of the study, this is a non-sensitizer.
	In vitro Cytotoxicity-ISO 10993	Not available.	Under the conditions of the study, the device extract was not cytotoxic.
Intended Use	-	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs 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
Color	-	Blue, and white	Blue
Texture	-	Finger Textured	Finger Textured
Size	Medical Glove Guidance Manual-Labeling	Extra Small	Extra Small
		Small	Small
		Medium	Medium
		Large	Large
		Extra Large	Extra Large
Single Use	Medical Glove Guidance Manual-Labeling	Single use	Single use

7.0 Summary of Non-Clinical Performance Data

The non-clinical performance test results for the subject device met the acceptance criteria in the standard or test method for dimension, physical properties, thickness,

freedom from holes, powder residues, chemotherapy permeation, and biocompatibility testing.

8.0 Summary of Clinical Performance Data

Not applicable- clinical data is not needed for the intended use of this subject device.

9.0 Conclusion

Based on intended use, technological characteristics and non-clinical performance data, the Non-Sterile Powder Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs is substantially equivalent to the predicate device K151750.