DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 9, 2016

Eco Medi Glove Sdn. Bhd.
Suresh Kumar
Quality Assurance Manager
Lot 23826, Jalan Tembaga Kuning
Kamunting Raya, Industrial Estate
Taiping, 34600 MY

Re: K161187
Trade/Device Name: EMG Blue Nitrile Examination Gloves Powder Free with Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: July 28, 2016
Received: August 11, 2016

Dear Suresh Kumar:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Division 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)*
K161187

Device Name
EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free patient eaxmination 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 and for use with chemotherapy drugs.In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drugs and Concentration	Minimum Breakthrough Detection Time (Min), μg/cm²/minute
1) Carmustine (BCNU)(3.3mg/ml)	1.3 minutes
2) Cyclophosphamide (20mg/ml)	> 240 minutes
3) Cytarabine (100mg/ml)	> 240 minutes
4) Doxorubicin Hydrochloride (2mg/ml)	> 240 minutes
5) Etopside (20mg/ml)	> 240 minutes
6) Fluorouracil (50mg/ml)	> 240 minutes
7) Methorexate (25mg/ml)	> 240 minutes
8) Paclitaxel (6mg/ml)	> 240 minutes
9) Thiotepa (10mg/ml)	67.8 minutes

The Maximum testing time is 240 Minutes.Please Note that the following drugs have extremely low Permeation time,
Carmustine (BCNU) (3.3mg/ml)-Minimum breakthrough detection time : 1.3 μg/cm²/minute
Thiotepa (10mg/ml) -Minimum breakthrough detection time : 67.8 μg/cm²/minute

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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ECO Medi Glove Sdn. Bhd. (815262-D)
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510(K) Summary
EMG Blue Nitrile Examination Gloves Powder Free with Tested for use with Chemotherapy Drugs

1.0 Submitter :

Company Name : ECO MEDI GLOVE SDN. BHD.

Company Address : Lot 23826,Jalan Tembaga Kuning
Kamunting Raya Industrial Estate,
34600,Kamunting Perak
Malaysia.

Contact Person : Mr Suresh Kumar

Telephone No : 603-60283033

Email : suresh@ecomediglove.com.my

2.0 Preparation Date : 1st September 2016

3.0 Name of the Device

Trade Name / Proprietary Name : EMG Blue Nitrile Examination Gloves
Powder Free with tested for use with
Chemotherapy drugs.

Device Name : Nitrile Patient Examination gloves.

Device Classification Name : Patient Examination gloves (21 CFR 880.6250).

Device Class : Class I.

Product Code : Nitrile-LZA and LZC.

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4.0) Identification of The Legally Marketed Device :

EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy drugs,LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.It is equivalent to K141982, Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non Sterile, Tested for use with Chemotherapy Drugs

5.0 Device Description

The subject device in this 510(k) Notification is EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy drugs. The subject device is a patient examination glove made from nitrile latex compound, Blue colour, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs.

The Blue Nitrile Medical Examination Gloves ,Powder Free, 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 (product Code LZA) and is used with chemotherapy drugs (Product code LZC). The subject device is substantially equivalent to the legally marketed Nitrile Medical Examination Gloves (product Code LZA and LZC).

6.0 Specification for Nitrile gloves:
6.1 Dimension and Thickness of Gloves

Dimension	Size S	Size M	Size L	Size XL
Overall Length (mm) (Minimum)	230	230	230	230
Width (± 5mm)	85	95	105	115
Thickness at Palm (mm) (Minimum)	0.05	0.05	0.05	0.05
Thickness at Finger Tip (mm)(Minimum)	0.05	0.05	0.05	0.05

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6.1.2 Gloves Physical Properties and Holes

Measurement	Before Ageing	After Aging at 70°C for 168 hrs @ 100°C for 22 hrs
Tensile Strength (MPa)	14min	14 Min
Ultimate Elongation (%)	500min	400min
Pin-hole Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

Gloves meet all the specification listed in ASTM D 6319-10

Characteristics	**Acceptance Criteria**	**EMG Blue Nitrile Examination Gloves Powder Free with tested for use with chemotherapy drugs,K161187**	**Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non Sterile, Tested for use with chemotherapy Drugs, K141982**	**Assessment Similarities and Differences**
Product Code	LZA and LZC	LZA and LZC	LZA and LZC	No different between subject and predicate devices.
Intended use	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. The device is for over-the-counter use. Intended use.	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. The device is for over-the-counter use.	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. The device is for over-the-counter use.	No different between subject and predicate devices.
Material use	Nitrile latex compound	Nitrile latex compound	Nitrile latex compound	No different between subject and predicate devices.

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Colour	Blue	Blue	Blue	No different between subject and predicate devices.
Sterility	Non sterile	Non sterile	Non sterile	No different between subject and predicate devices.
Single used	Single used	Single used	Single used	No different between subject and predicate devices.
Non Sterile	Non Sterile	Non Sterile	Non Sterile	No different between subject and predicate devices.
Dimensions	Overall Length (mm) Min 230 mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Meets ASTM D6319-10	Meets ASTM D6319-10	Subject devices and predicate device is different on the dimension. Subject devices is having thickness at palm and finger of 0.05mm (Min) and length with 230mm (Min).Predicate devices is with thickness at palm and finger of 0.07-0.10mm and length with min 240mm
Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70°C for**	Meets ASTM D6319-10	Meets ASTM D6319-10	No different between subject and predicate devices.

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	168 hrs @ 100°C for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min			
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	No different between subject and predicate devices.
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	No different between subject and predicate devices.
Biological Evaluation on Medical Device -Primary Skin Irritation Test		Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	No different between subject and predicate devices.
Biological Evaluation on Medical Device- Dermal Sensitization Assay		Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non- sensitizer.	No different between subject and predicate devices.
Resistance against Chemotherapy Drugs	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-05(2013)	1) Carmustine (3.3mg/ml or 3000ppm), Minimum Breakthrough detection time : 1.3 µg/cm²/minute 2) Cyclophosphamide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute	1) Carmustine (3.3mg/ml or 3000ppm), Minimum Breakthrough detection time: 15 µg/cm²/minute 2) Cyclophosphamide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute	Subject device was tested with 7 mandatory chemotherapy drugs and with addition 2 chemotherapy. Predicate device was tested with 7 mandatory chemotherapy drugs with additional of 5

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		3) Cytarabine (100mg/ml or 100,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 5) Etoposide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 6) Flourouracil (50mg/ml or 50,000), Minimum Breakthrough detection time: >240 µg/cm²/minute 7) Methorexate (25mg/ml or 25,000ppm), Minimum Breakthrough detection time: > 240 µg/cm²/minute 8) Paclitaxel (6mg/ml or 6,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 9) Thiotepa (10mg/ml or 10,000ppm), Minimum Breakthrough	3) Dacarbazine (10mg/ml) Minimum Breakthrough detection time: >240µg/cm²/minute 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 5) Etoposide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 6) Flourouracil (50mg/ml or 50,000), Minimum Breakthrough detection time: >240 µg/cm²/minute 7) Cisplatin (1 mg/ml) Minimum Breakthrough detection time: >240 µg/cm²/minute 8) Paclitaxel (6mg/ml or 6,000ppm), Minimum Breakthrough detection time: >240 µg/cm²/minute 9) Thiotepa (10mg/ml or 10,000ppm), Minimum Breakthrough	chemotherapy drugs.

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		detection time: 67.8 µg/cm²/minute	detection time: 2 µg/cm²/minute 10) Ifosfamide (50mg/ml) Minimum Breakthrough detection time: >240 µg/cm²/minute . 11) Mitoxantrone (2mg/ml) , Minimum Breakthrough detection time: >240 µg/cm²/minute 12) Vincristine Sulfate (1mg/ml) , Minimum Breakthrough detection time: >240 µg/cm²/minute	

7.0 Indications for Use

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 and for use with chemotherapy drugs . It is for over-the-counter use.

In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

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Chemotherapy Drug and concentration	Minimum Breakthrough detection time in Minutes,µg/cm²/minute
1)Carmustine (BCNU) (3.3mg/ml)	1.3 minutes
2)Cyclophosphamide (20mg/ml)	> 240 minutes
3)Cytarabine (100mg/ml)	> 240 minutes
4)Doxorubicin Hydrochloride (2 mg/ml)	> 240 minutes
5)Etoposide (20mg/ml)	> 240 minutes
6)Fluorouracil (50mg/ml)	> 240 minutes
7)Methorexate (25mg/ml)	> 240 minutes
8) Paclitaxel (6mg/ml)	> 240 minutes
9) Thiotepa (10mg/ml)	67.8 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml) - Minimum Breakthrough detection time 1.3 µg/cm²/minute.
Thiotepa (10mg/ml) – Minimum Breakthrough detection time 67.8 µg/cm²/minute.

8.0 Summary of the Technological Characteristics of the Device compared to the Predicate Device for substantial equivalent discussion

There are no differences in technological characteristics of the subject device compare with the predicate device.

The gloves are made from nitrile latex compound, Blue colour, Powder free and non-sterile. The gloves met all the specifications in ASTM D6319-10 Standard specification for Nitrile Examination Gloves as well Biological Evaluation on medical device. Additionally, the gloves have been tested for permeability to chemotherapy drugs.

Based on the intended uses, physical properties and technological characteristics, the subject device is as safe and effective as a legally marketed device- K141982, Dermagrip Powder free Blue Nitrile Patient Examination Gloves Tested for use with chemotherapy Drugs and its does not raise different questions of safety and effectiveness.

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9.0 Conclusion

Based on intended uses, technological characteristics and non – clinical performance data, the EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy Drugs is substantially equivalent to the predicate device (K141982).