DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 7, 2017

ECO Medi Glove Sdn. Bhd.
Suresh Kumar
Official Correspondent
Lot 23826, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Kamunting Perak, 34600 Malaysia

Re: K171339
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: Class I
Product Code: LZA, LZC
Dated: May 15, 2017
Received: May 19, 2017

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,

Mark S. Fellman -S

for

Lori A. 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)*
K171339

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

Indications for Use *(Describe)*
A powder-free patient examination glove is a disposable device intended for use medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner and use for use with chemotherapy drugs.
In addition these gloves were tested for use with chemotherapy drugs in accordance 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/minutes
1) Carmustine (BCNU)(3.3 mg/ml)	24.0 Minutes
2)Cyclophoshamide (20 mg/ml)	> 240 Minutes
3)Doxorubicin Hydrochloride (2mg/ml)	> 240 Minutes
4)Etoposide (20mg/ml)	> 240 Minutes
5)Fluorouracil (50mg/ml)	> 240 Minutes
6)Methorexate (25mg/ml)	> 240 Minutes
7)Paclitaxel (6mg/ml)	> 240 Minutes
8)Thiotepa (10mg/ml)	56.9 Minutes
9)Carboplatin (10mg/ml)	> 240 Minutes
10)Cisplatin (1 mg/ml)	> 240 Minutes
11)Dacarabazine (1 mg/ml)	> 240 Minutes
12)Ifosfamide (5 mg/ml)	> 240 Minutes
13)Mitomycin (0.5mg/ml)	> 240 Minutes
14)Mitoxantrone (2 mg/ml)	> 240 Minutes
15)Vincristine Sulfate (1 mg/ml)	> 240 Minutes

The Maximum testing is 240 minutes. Please note that the following drugs have extremely low Permeation time,
Carmustine (BCNU)(3.3 mg/ml) - Minimum breakthrough detection time : 24.0 minutes
Thiotepa (10mg/ml) - Minimum breakthrough detection time : 56.9 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.

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ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

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 : 4th July 2017

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 K161187, EMG Blue Nitrile Examination Glove Powder Free with 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 color, 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).

6.1 Specification for Nitrile gloves:

6.2 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. K171339**	**EMG Blue Nitrile Examination Gloves, Powder Free with tested for use with chemotherapy drugs, K161187**	**Comparison**
Product Code	LZA and LZC	LZA and LZC	LZA and LZC	Same
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.	Same
Material use	Nitrile latex compound	Nitrile latex compound	Nitrile latex compound	Same
Color	Blue	Blue	Blue	Same
Sterility	Non sterile	Non sterile	Non sterile	Same
Single used	Single used	Single used	Single used	Same

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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	Size : Medium Palm Width: 98 mm Length : 247 mm Finger Thickness : 0.08mm Palm Thickness : 0.05mm Meets ASTM D6319-10	Size : Medium Palm Width: 99 mm Length : 247 mm Finger Thickness : 0.11mm Palm Thickness : 0.07mm Meets ASTM D6319-10	Same
Physical properties	**Before Ageing** Tensile Strength (MPa) = Min 14 Mpa Ultimate Elongation (%) = Min 500 % **After Aging at 70ºC for 168 hrs @ 100ºC for 22 hrs** Tensile Strength (MPa) = Min 14 Mpa Ultimate Elongation (%) = Min 400 %	Tensile strength (Mpa) : Before aging : 25.45Mpa After Accelerated aging: 26.33Mpa Ultimate Elongation(%): Before aging:600% After aging : 550% Meets ASTM D6319-10	Tensile strength (Mpa) : Before aging : 25.45Mpa After Accelerated aging: 26.33Mpa Ultimate Elongation(%): Before aging:600% After aging : 550% Meets ASTM D6319-10	Same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	AQL 2.5 Meets ASTM D5151-06	AQL 2.5 Meets ASTM D5151-06	Same
Residual Powder	≤ 2.0 mg/glove	Average 0.17 mg/glove Meets ASTM D6124-06	Average 0.19 mg/glove Meets ASTM D6124-06	Same
Biological Evaluation on Medical Device -Primary Skin Irritation Test	ISO 10993-10:2010	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.	Same
Biological Evaluation on Medical Device- Dermal Sensitization Assay	ISO 10993-10:2010	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.	Same

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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 : 24 minutes 2) Cyclophosphamide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 minutes 3) Cisplatin (1.0mg/ml or 1,000ppm), Minimum Breaktrough detection time: >240 minutes 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Minimum Breakthrough detection time: >240 minutes 5) Etoposide (20mg/ml or 20,000ppm), Minimum Breakthrough detection time: >240 minutes 6) Flourouracil (50mg/ml or 50,000), Minimum Breakthrough detection time: >240 minutes	1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 1.3 minutes. 2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 minutes. 3) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : >240 minutes. 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 minutes. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 minutes. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 minutes. 7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 minutes. 8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 minutes.	Subject device was tested with 7 mandatory chemotherapy drugs with additional 8 chemotherapy drugs. Predicate device was tested with 7 mandatory chemotherapy drugs with additional of 2 chemotherapy drugs.

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		7) Methorexate (25mg/ml or 25,000ppm), Minimum Breakthrough detection time: > 240 minutes 8) Paclitaxel (6mg/ml or 6,000ppm), Minimum Breakthrough detection time: >240minutes 9) Thiotepa (10mg/ml or 10,000ppm), Minimum Breakthrough detection time: 56.9 minutes 10) Ifosfamide (50mg/ml) Minimum Breakthrough detection time: >240 minutes . 11) Mitoxantrone (2mg/ml) , Minimum Breakthrough detection time: >240 minutes 12) Vincristine Sulfate (1mg/ml) , Minimum Breakthrough detection time: >240 minutes 13) Carboplatin (10.0mg/ml), Minimum Breakthrough detection time: >240 minutes	9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time: 67.8 minutes.	

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		14) Dacarbazine (DTIC) (10.0mg/ml) Minimum Breakthrough detection time: >240 minutes 15) Mitomicin C (0.5mg/ml) Minimum Breakthrough detection time: >240 minutes		

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 .

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 Drug and concentration	**Minimum Breakthrough detection time in Minutes,µg/cm²/minute**
1)Carmustine (BCNU) (3.3mg/ml)	**24 minutes**
2)Cyclophosphamide (20mg/ml)	**> 240 minutes**
3)Cytarabine (10mg/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)	**56.9 minutes**
10) Cisplatin (1.0mg/ml)	**> 240 minutes**

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11) Dacarbazine (DTIC) (10.0mg/ml)	**> 240 minutes**
12) Ifosfamide (50.0mg/ml)	**> 240 minutes**
13) Mitomycin C (0.5mg/ml)	**> 240 minutes**
14) Mitoxantrone (2.0mg/ml)	**> 240 minutes**
15) Vincristine Sulfate (1.0mg/ml)	**> 240 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 24 Minutes

Thiotepa (10mg/ml) – Minimum Breakthrough detection time 56.9 minutes.

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 color, 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.

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 as safe, as effective, and performs as well as the legally marketed predicate device, K161187.