



Food and Drug Administration  
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June 23, 2016

Eco Medi Glove Sdn. Bhd.  
Mr. Suresh Kumar  
Official Correspondent  
Lot 23826, Jalan Tembaga Kuning,  
Kamunting Raya Industrial Estate  
Taiping Perak, 34600  
MALAYSIA

Re: K152937

Trade/Device Name: EMG Powder Free Nitrile Examination (Blue) Glove with Peppermint Scented  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA  
Dated: May 2, 2016  
Received: May 13, 2016

Dear Mr. 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,

*Tejashri Purohit-Sheth, M.D.*

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

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K152937

Device Name  
EMG Powder Free Nitrile Examination (Blue) Glove with Peppermint scented

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 hands or finger to prevent contamination between patient and examiner

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)

(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 Powder Free Nitrile Examination Glove (Blue) with Peppermint Scented.**

**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** : 2<sup>nd</sup> June 2016 .

**3.0 Name of the Device**

Trade Name / Proprietary Name : EMG Powder Free Nitrile Examination Glove  
(Blue) with Peppermint Scented

Device Name : Nitrile Patient Examination gloves .

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

Device Class : Class I .

Product Code : LZA .

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### **4.0 Identification of The Legally Marketed Device :**

Class I patient Examination gloves, Powder Free, LZA which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250. It is equivalent to K070097, Powder Free Nitrile Examination Glove, Peppermint Scented , blue Color

### **5.0 Description of Device :**

Blue Nitrile Examination gloves powder free with Peppermint Scented , non sterile, as described in this 510(k) Notification is substantially equivalent to the current class I patient examination gloves with product Code LZA (21CFR 880.6250). It meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. They are made nitrile from nitrile latex compound, Blue color, Powder free and non sterile.

### **6.0 Executive summary :**

EMG Powder Free Nitrile Examination Glove (Blue) with Peppermint Scented is a disposable glove made of nitrile latex compound Blue color powder free. This Blue Nitrile Examination Gloves Powder Free with Peppermint Scented 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 .

#### **6.1.1 Specification for Nitrile gloves:**

##### **6.1.1.1 Dimension and Thickness of Gloves .**

<b>Dimension</b>	<b>Size S</b>	<b>Size M</b>	<b>Size L</b>	<b>Size XL</b>
Overall Length (mm)	230min	230min	230min	230min
Width ( $\pm$ 5mm)	85	95	105	115
Thickness at Palm (mm)	0.05min	0.05min	0.05min	0.05min
Thickness at Finger Tip (mm)	0.05min	0.05min	0.05min	0.05min

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### 6.3.2.2 Gloves Physical Properties and Holes

Measurement	Before Aging	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.

### 7.0 Intended use of the Device :

A Powder-free patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner .

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

There is no different technology characteristics compared to the predicate device .  
Gloves are made from nitrile latex compound, Blue color, powder free and non sterile. It is equivalent to K070097, Powder Free Nitrile Examination Glove, Peppermint Scented, blue Color

Characteristics	Acceptance Criteria	EMG Powder Free Nitrile Examination Glove (Blue) with Peppermint Scented	Powder Free Nitrile Examination Glove, Peppermint Scented , blue Color <b>510K#:070097</b>
Product Code	LZA	LZA	LZA
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.	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.	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.

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	The device is for over-the-counter use.	The device is for over-the-counter use.	The device is for over-the-counter use.
Material use	Not made from Natural Rubber Latex.	Nitrile latex compound.	Nitrile latex compound.
Colour	Peppermint Scented , blue Color	Peppermint Scented , blue Color	Peppermint Scented , blue Color
Sterility	Non sterile	Non sterile	Non sterile
Dimensions	Overall Length (mm) = Min 230mm  Width (± 5mm) <b>Size S = 85mm</b> <b>Size M = 95mm</b> <b>Size L = 105mm</b> <b>Size XL = 115mm</b>  Thickness at Palm (mm) = Min 0.05min  Thickness at Finger Tip (mm) = Min 0.05min	Meets ASTM D6319-10	Meets ASTM D6319-10

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Physical properties	<p><b>Before Aging</b></p> <p>Tensile Strength (MPa) = Min 14min</p> <p>Ultimate Elongation (%) = Min 500min</p> <p><b>After Aging at 70°C for 168 hrs @ 100°C for 22 hrs</b></p> <p>Tensile Strength (MPa) = Min 14min</p> <p>Ultimate Elongation (%) = Min 400min</p>	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06
Biological Evaluation on Medical Device -Primary Skin Irritation Test .	The test article is a non-irritant per ISO 10993-10.	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.
Biological Evaluation on Medical Device- Dermal Sensitization Assay .	The test article is a non-sensitizer per ISO 10993-10.	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.

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**9.0) Substantial Equivalent Based on Assessment of Non-Clinical Performance data**

Performance testing was completed in accordance with ASTM D6319-10 , ASTM D5151-06, and ASTM D6124-06. The glove meet standards requirement referenced in section 6.0 above. Biocompatibility testing per ISO 10993-10:2010 indicates that the subject gloves are non-sensitizing and non-irritating under the conditions tested

**9.0 Conclusion**

The conclusions drawn from the nonclinical and clinical tests demonstrate that EMG Powder Free Nitrile Examination (Blue) Glove with Peppermint Scented is as safe, as effective, and performs as well as the legally marketed predicate device K070097 Powder Free Nitrile Examination Glove, Peppermint Scented, Blue Color