



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
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October 17, 2014

Eco Medi Glove SDN BHD  
Mr. Suresh Kumar  
Quality Assurance Manager  
Lot 23826, Jalan Tembaga Kuning  
Kamunting Raya Industrial Estate  
Taiping, Perak Darul Ridzuan, Malaysia 34600

Re: K141579

Trade/Device Name: EMG Black Nitrile Medical Examination Glove Powder Free

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA

Dated: September 10, 2014

Received: September 12, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.  
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Division of Anesthesiology, General Hospital,  
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Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141579

Device Name

EMG Black Nitrile Medical Examination Glove Powder Free

Indications for Use (Describe)

A Powder Free Patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand 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**

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**510(K) Summary**  
**EMG Black Nitrile Medical Examination Glove Powder Free .**

**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** : 03<sup>th</sup> October 2014 .

**3.0 Name of the Device**

Trade Name / Proprietary Name : EMG Black Nitrile Medical Examination  
Gloves Powder Free .

Device Name : Nitrile Patient Examination gloves .

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

Device Class : Class I .

Product Code : Nitrile-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 K112924, RS Black Nitrile Medical Examination Gloves Powder Free ( Non-Sterile ) .

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

Black Nitrile Medical Examination gloves powder free, 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, Black colour, powder free and non sterile.

### **6.0 Executive summary :**

EMG Black Nitrile Medical Examination Glove Powder Free is a disposable glove made of nitrile latex compound Black colour powder free. This Black 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 .

#### **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 (± 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 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.

### 7.0 Intended use of the Device :

A Powder-free patient examination gloves 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. It is for over-the-counter use .

### 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, Black colour, powder free and non sterile. It is equivalent to K 112924, RS Black Nitrile Medical Examination Gloves Powder Free ( Non-Sterile ) .

Characteristics	Acceptance Criteria	EMG Black Nitrile Medical Examination Gloves Powder Free,K141579	RS Black Nitrile Medical Examination Gloves Powder Free ( Non-Sterile ) K112924
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. 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.	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.

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Material use	Not made from Natural Rubber Latex.	Nitrile latex compound.	Nitrile latex compound.
Colour	Black	Black	Black
Sterility	Non sterile	Non sterile	Non sterile Section 2A-3
Dimensions	Overall Length (mm) = Min 230mm  Width ( $\pm$ 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 0.05mm  Thickness at Finger Tip (mm) = Min 0.05mm	Meets ASTM D6319-10	Meets ASTM D6319-10

Physical properties	<b>Before Ageing</b>  Tensile Strength (MPa) = Min 14min  Ultimate Elongation (%) = Min 500min  <b>After Aging at 70°C for 168 hrs @ 100°C for 22 hrs</b>  Tensile Strength (MPa) = Min 14min Ultimate Elongation (%) = Min 400min	Meets ASTM D6319-10	Meets ASTM D6319-10
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Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06
Residual Powder	$\leq 2.0$ mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06
Biological Evaluation on Medical Device - Primary Skin Irritation Test .	Test Article was non irritant.	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 .	Test Article was non sensitizer.	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.

**9.0 Conclusion**

It can be concluded that EMG Black Nitrile Medical Examination Gloves Powder Free and predicate devices are substantially equivalent base on intended uses, physical properties, technological characteristics and non-clinical performance .