



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 18, 2014

PT Smart Glove Indonesia  
Mr. Khon Pu Foo  
Managing Director  
JL. Pelita Raya No. 5-7  
Kimstar, Tanjung Morawa  
Medan, North Sumatera  
INDONESIA 20362

Re: K133699

Trade/Device Name(s): Powder-Free Green Polychloroprene Examination Gloves  
Powder-Free Blue Polychloroprene Examination Gloves  
Powder-Free Brown Polychloroprene Examination Gloves

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LZA

Dated: May 26, 2014

Received: June 5, 2014

Dear Mr. Pu Foo:

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" (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 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,

*Tejasri Purohit-Sheth, M.D.*  
Tejasri 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

**ATTACHMENT # 2**

**Indications for Use**

**Applicant :** Smart Glove Indonesia

**510(k) Number (if known):** K133699

**Device Name:** Powder-Free Green Polychloroprene Examination Gloves

**Indications For Use:**

A patient examination glove is a disposable device intended for medical purposes that worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_√\_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Digitally signed by Terrell A. Cunningham -S**

**Date: 2014.07.17 13:29:13 -04'00'**

Concurrence of CDRH, Office of Device Evaluation (ODE)

**ATTACHMENT # 2a**

**Indications for Use**

**Applicant :** Smart Glove Indonesia

**510(k) Number (if known):** K133699

**Device Name:** Powder-Free Blue Polychloroprene Examination Gloves

**Indications For Use:**

A patient examination glove is a disposable device intended for medical purposes that worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**ATTACHMENT # 2b**

**Indications for Use**

**Applicant :** Smart Glove Indonesia

**510(k) Number (if known):** K133699

**Device Name:** Powder-Free Brown Polychloroprene Examination Gloves

**Indications For Use:**

A patient examination glove is a disposable device intended for medical purposes that worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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