



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

November 2, 2015

PT. Medisafe Technologies
Anil Taneja
EVP
Jl. Batang Kuis, Gg Tambak Rejo Pasar IX, Desa Buntu Bedimar
Tanjung Morawa,
Medan 20362, Sumatera Utara, INDONESIA

Re: K142941

Trade/Device Name: Powder-free Polyisoprene Sterile Surgical Gloves In White Color
Tested For Use With Chemotherapy Drugs; Powder-free Polyisoprene
Sterile Surgical Gloves In Green Color

Regulation Number: 21 CFR 878.4460

Regulation Name: Surgeon's Glove

Regulatory Class: I

Product Code: KGO, LZC

Dated: August 23, 2015

Received: September 28, 2015

Dear Mr. Taneja:

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 Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K142941

Device Name
Powder-Free Polyisoprene Sterile Surgical Gloves in White Color Tested for Use with Chemotherapy Drugs.

Indications for Use (Describe)

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Test Chemotherapy Drug	Concentration (mg/ml)	Minimum Breakthrough Detection Time (minutes)
Camustine	3.3 mg/ml	15.2
Cisplatin	1.0 mg/ml	> 240 min
Cyclophosphamide	20.0 mg/ml	> 240 min
Dacarbazine	10.0 mg/ml	> 240 min
Doxorubicin Hydrochloride	2.0 mg/ml	> 240 min
Etoposide	20.0 mg/ml	> 240 min
Fluorouracil	50.0 mg/ml	> 240 min
Ifosfamide	50.0 mg/ml	> 240 min
Mechloroethamine HCl	1.0 mg/ml	> 240 min
Melphalan	5.0 mg/ml	> 240 min
Methotrexate	25.0 mg/ml	> 240 min
Paclitaxel	6.0 mg/ml	> 240 min
Thiotepa	10.0 mg/ml	15.5
Vincristine Sulfate	1.0 mg/ml	> 240 min

Please note that the following drugs have extremely low permeation times;

1. Carmustine (3.3 mg/ml) : 15.2 minutes.
2. Thiotepa (10.0 mg/ml) : 15.5 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)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)
K142941

Device Name
Powder-Free Polyisoprene Sterile Surgical Gloves in Green Color.

Indications for Use (Describe)

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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)

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