March 28, 2019

PT. Medisafe Technologies
Punitha Samy
Group Regulatory Affairs Manager
JI Batang Kuis, Gg Tambak Rejo Pasar IX, Desa Buntu Bedimbar
Tanjung Morawa, Medan, 20362 Id

Re: K182176
Trade/Device Name: Polychloroprene Powder Free Sterile Surgical Gloves, White, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO, LZC
Dated: February 22, 2019
Received: March 1, 2019

Dear Punitha Samy:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182176

Device Name
Polychloroprene Powder Free Sterile Surgical Gloves, White, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
This surgeon's glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. This glove is also tested for use with Chemotherapy Drugs. The Chemotherapy Drugs and its permeation time is listed as below.

Test Chemotherapy Drug and Concentration	Breakthrough Detection Time (Minutes)
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	37.5 (47.8, 38.3, 37.5)
Cisplatin 1.0 mg/ml (1,000ppm)	>240 min
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	>240 min
Dacarabzine (DTIC) 10.0 mg/ml (10,000 ppm)	>240 min
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	>240 min
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	>240 min
Fluorouracil 50.0 mg/ml (50,000 ppm)	>240 min
Ifosfamide 50.0 mg/ml (50,000 ppm)	>240 min
Methotrexate 25 mg/ml (25, 000 ppm)	>240 min
Mechlorethamine HCI 1.0 mg/ml (1,000 ppm)	>240 min
Melphalan 5 mg/ml (5,000 ppm)	>240 min
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	>240 min
Thiotepa 10.0 mg/ml (10,000 ppm)	58.3 (69.8, 68.6, 58.3)
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240 min

Please note that the following drugs have low permeation times:
Carmustine (3.3 mg/ml): 37.5 minutes ThioTEPA (10.0 mg/ml): 58.3 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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