September 11, 2020
Medline Industries, Inc
Jennifer Mason
Senior Regulatory Affairs Specialist
Three Lake Drive
Northfield, Illinois 60093

Re: K191915
Trade/Device Name: SensiCare Sterile Power-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs) - Natural and Green Colors
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC

Dear Jennifer Mason:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 6, 2020. Specifically, FDA is updating this SE Letter (e.g. Incorrect Contact information) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Vacant, OHT4: Office of Surgical and Infection Control Devices, (301) 796 – 6298, Elizabeth.Claverie@fda.hhs.gov.

Sincerely,

Ryan Ortega -S

For Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 6, 2020

Medicine Industries, Inc
Jennifer Mason
Senior Regulatory Affairs Specialist
Three Lake Drive
Northfield, Illinois 60093

Re: K191915
Trade/Device Name: SensiCare Sterile Power-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs) - Natural and Green Colors
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: February 3, 2020
Received: February 4, 2020

Dear Jennifer Mason:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA Elizabeth F. Claverie -S

Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191915

Device Name
SensiCare PI Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs) - Natural Color

Indications for Use *(Describe)*
This surgeon's glove is a device made of synthetic rubber latex intended to be worn by surgeons and or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

The following chemicals have been tested with these gloves

Bleomycin 15 mg/ml >240 minutes
Busulfan 6 mg/ml >240 minutes
Carboplatin 10.0 mg/ml >240 minutes
Carmustine (BCNU) 3.3 mg/ml 22.5 (23.4, 23.8, 22.5) minutes
Cisplatin 1.0 mg/ml >240 minutes
Cyclophosphamide (Cytoxan) 20 mg/ml >240 minutes
Dacarbazine (DTIC) 10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Epirubicin (Ellence) 2 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fludarabine 25.0 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Idarubicin 1.0 mg/ml >240 minutes
Ifosfamide 50.0 mg/ml >240 minutes
Mechlorethamine HCI 1.0 mg/ml >240 minutes
Melphalan 5 mg/ml >240 minutes
Methotrexate 25 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Mitoxantrone 2.0 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Paraplatin 10 mg/ml >240 minutes
Rituximab 10 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 24.4 (25.3, 24.4, 25.6) minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa

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.

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:

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

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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)*
K191915

Device Name
SensiCare PI Sterile Powder-Free Polymer Coated Polyisoprene Surgical Glove, Coated with Aloe Vera (Tested for Use with Chemotherapy Drugs) - Green Color

Indications for Use *(Describe)*
The surgeon's glove is a device made of synthetic rubber latex intended to be worn by surgeons and or operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

The following chemicals have been tested with these gloves

Bleomycin 15 mg/ml >240 minutes
Busulfan 6 mg/ml >240 minutes
Carboplatin 10.0 mg/ml >240 minutes
Carmustine (BCNU) 3.3 mg/ml 13.7 (14.4, 14.4, 13.7) minutes
Cisplatin 1.0 mg/ml >240 minutes
Cyclophosphamide (Cytoxan) 20 mg/ml >240 minutes
Dacarbazine (DTIC) 10.0 mg/ml >240 minutes
Doxorubicin Hydrochloride 2.0 mg/ml >240 minutes
Epirubicin (Ellence) 2 mg/ml >240 minutes
Etoposide (Toposar) 20.0 mg/ml >240 minutes
Fludarabine 25.0 mg/ml >240 minutes
Fluorouracil 50.0 mg/ml >240 minutes
Idarubicin 1.0 mg/ml >240 minutes
Ifosfamide 50.0 mg/ml >240 minutes
Mechlorethamine HCI 1.0 mg/ml >240 minutes
Melphalan 5 mg/ml >240 minutes
Methotrexate 25 mg/ml >240 minutes
Mitomycin C 0.5 mg/ml >240 minutes
Mitoxantrone 2.0 mg/ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 minutes
Paraplatin 10 mg/ml >240 minutes
Rituximab 10 mg/ml >240 minutes
Thiotepa 10.0 mg/ml 13.8 (13.8, 16.4, 14.8) minutes
Vincristine Sulfate 1.0 mg/ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa

Type of Use *(Select one or both, as applicable)*

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