DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 31, 2016

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, Illinois 60060

Re: K152428
Trade/Device Name: SensiCare PI Surgical Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: March 3, 2016
Received: March 4, 2016

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. 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 Keith, M.S.
Division 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152428

Device Name
SensiCare PI Surgical Gloves

Indications for Use *(Describe)*
The SensiCare PI surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
The following chemicals have been tested with these gloves.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

Carmustine (BCNU) 3.3 mg/ml (3,300 ppm) 10.1 min. (10.1, 10.1, 10.1)
Cisplatin 1.0 mg/ml (1,000 ppm) 240 min.
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm) 240 min.
Cytarabine 100 mg/ml (100,000 ppm) 240 min.
Dacarbazine (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.
Mitomycin C 0.5 mg/ml (500 ppm) 240 min.
Mitoxantrone 2.0 mg/ml (2,000 ppm) 240 min.
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm) 240 min.
Thiotepa 10.0 mg/ml (10,000 ppm) 11.6 min. (20.2, 21.5, 11.6)
Vincristine Sulfate 1.0 mg/ml (1,000 ppm) 240 min.

Please note that the following drugs have extremely low permeation time of less than 30 minutes: Carmustine (3.3 mg/ml) has a minimum breakthrough time of 10.1 minutes; Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 11.6 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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

SECTION 5
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060

Registration Number: 1417592

Contact Person
Jennifer Mason
Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date
March 31, 2016

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: SensiCare PI Surgical Gloves
Proprietary Name: SensiCare PI Surgical Gloves
Common Name: Surgeon's gloves
Classification Name: Surgeon's gloves
Product Code: KGO, LZC
Regulatory Class: Class I
Regulation #: 21 CFR 878.4460
Classification Panel: General Hospital

Predicate Device
Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs
K110272

Device Description
The SensiCare PI Surgical Gloves are disposable powder-free surgical gloves that are intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination. The gloves are made with

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

polyisoprene and are cream in color. The SensiCare PI Surgical Gloves are available in a smooth grip and are constructed with a beaded cuff. The gloves have been tested for use with chemotherapy drugs per ASTM D6978.

Indications for Use:

The SensiCare PI surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemicals have been tested with these gloves.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes

Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	10.1 min. (10.1, 10.1, 10.1)
Cisplatin 1.0 mg/ml (1,000 ppm)	240 min.
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	240 min.
Cytarabine 100 mg/ml (100,000 ppm)	240 min.
Dacarbazine (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.
Mitomycin C 0.5 mg/ml (500 ppm)	240 min.
Mitoxantrone 2.0 mg/ml (2,000 ppm)	240 min.
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	240 min.
Thiotepa 10.0 mg/ml (10,000 ppm)	11.6 min. (20.2, 21.5, 11.6)
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	240 min.

Please note that the following drugs have extremely low permeation time of less than 30 minutes: Carmustine (3.3 mg/ml) has a minimum breakthrough time of 10.1 minutes; Thiotepa (10.0 mg/ml) has a minimum breakthrough time of 11.6 minutes.

Summary of Technological Characteristics

The SensiCare PI Surgical Glove is substantially equivalent to the predicate, K110272, Sterile Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs. Both gloves have the same intended use, same material and the same device performance.

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	SensiCare PI Surgical Gloves	Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs	N/A
510(k) Reference		K110272	N/A
Product Owner	Medline Industries, Inc.	Cardinal Health	Different
Product Code	KGO	KGO	Substantially Equivalent
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Substantially Equivalent
Intended Use	The SensiCare PI surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Warning: Do not use with Carmustine and Thiotepa	This powder-free surgeon's glove is a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM d 6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Substantially Equivalent
Sizes	5 ½ , 6, 6 ½ ,7, 7 ½ , 8, 8 ½, 9	5 ½ , 6, 6 ½ ,7, 7 ½ , 8, 8 ½, 9	Substantially Equivalent
Materials	Polyisoprene	Polyisoprene	Substantially Equivalent
Colorant	Yes – cream colored. Contains a blend of three colorants (naphthos AS red, azo yellow and carbon black)	Yes – cream colored	Substantially Equivalent
Dimensions - Length	Meets ASTM D 3577 270mm min.	Meets ASTM D 3577 270mm min.	Substantially Equivalent
Dimensions - Width	Meets ASTM D 3577 5 ½ - 70±6mm 6 - 76±6mm 6 ½ - 83±6mm 7 - 89±6mm 7 ½ - 95±6mm	Meets ASTM D 3577 5 ½ - 70±6mm 6 - 76±6mm 6 ½ - 83±6mm 7 - 89±6mm 7 ½ - 95±6mm	Substantially Equivalent

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

	8 - 102±6mm 8 ½ - 108±6mm 9 - 114±6mm	8 - 102±6mm 8 ½ - 108±6mm 9 - 114±6mm	
Dimensions – Finger Thickness	Meets ASTM D3577 0.10mm min	Meets ASTM D3577 0.10mm min	Substantially Equivalent
Dimensions – Palm Thickness	Meets ASTM D3577 0.10mm min	Meets ASTM D3577 0.10mm min	Substantially Equivalent
Dimension – Cuff Thickness	Meets ASTM D3577 0.10mm min	Meets ASTM D3577 0.10mm min	Substantially Equivalent
Physical Properties	Meets ASTM D3577 Before Aging Tensile Strength - 17 MPa min Ultimate Elongation – 650% min Stress at 500% Elongation – 7.0 MPa min	Meets ASTM D3577 Before Aging Tensile Strength - 17 MPa min Ultimate Elongation – 650% min Stress at 500% Elongation – 7MPa min	Substantially Equivalent
	Meets ASTM 3577 After Aging Tensile Strength – 12 MPa min Ultimate Elongation – 490% min	Meets ASTM 3577 After Aging Tensile Strength – 12 MPa min Ultimate Elongation – 490% min	Substantially Equivalent
Freedom from Holes	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5	Substantially Equivalent
Powder or Powder-free	Powder-free	Powder-free	Substantially Equivalent
Residual Powder	<2mg of residual powder when tested in accordance with ASTM D3577	<2mg of residual powder when tested in accordance with ASTM D3577	Substantially Equivalent
Tested for Use with Chemotherapy Drugs	Yes	Yes	Substantially Equivalent
Chemotherapy Drugs Tested	[redacted]	Blenoxane (15mg/ml)>240	Similar
	[redacted]	Busulfan (6mg/ml) >240	
	Carmustine 10.1	Carmustine (3.3mg/ml) 0.37	
	Cisplatin >240	Cisplatin (1.0mg/ml) >240	
	Cytarabine >240	Cytarabine (100mg/ml) >240	
	Cyclophosphamide >240	Cyclophospharmide (20mg/ml) >240	
	Dacarbazine >240	Dacarabazine (10mg.ml) >240	
	Doxorubicin >240	Doxorubicin (2.0mg.ml) >240	
	[redacted]	Ellence (25mg/ml) >240	
	Etoposide >240	Etoposide (20mg/ml) >	
	[redacted]	Fludarabine (25mg.ml) >240	
	Fluorouracil >240	Fluorouracil (50mg.ml) >240	

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

	[redacted]	Idarubicin (1mg/ml) >240	
	Ifosfamide >240	Ifosfamide (50mg/ml) >240	
	[redacted]	Mechlorethamine HCI (1mg.ml) >240	
		Melphalan (5mg.ml) >240	
	Methotrexate >240	Methotrexate (25 mg.ml) >240	
	Mitoxantrone >240	Mitoxantrone (2mg.ml) >240	
	Mitomycin C >240	Mitomycin C (0.5mg.ml) >240	
	Paclitaxel >240	Paclitaxel (6.0 mg/ml) >240	
	[redacted]	Paraplatin (10mg.ml) >240	
		Rituximab (10mg/ml) >240	
	Thiotepa 11.6	Thiotepa (10mg/ml) 0.44	
	[redacted]	Trisenox (0.1mg.ml) >240	
	Vincristine sulfate >240	Vincristine sulfate (1mg/ml) >240	
Sterile or Non-sterile	Sterile	Sterile	Substantially Equivalent
Sterilization Method	Gamma 10^{-6}	Gamma	Substantially Equivalent
Primary Skin Irritation	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Meets ISO 10993-10	Substantially Equivalent
Sensitization (Guinea Pig Maximization Test)	Under the conditions of the study (per ISO 10993-10), the device is not a sensitizer	Meets ISO 10993-10	Substantially Equivalent
Elements Contained on Product Labeling	[redacted]		
• **Product Identifier**	Yes	Yes	Substantially Equivalent
• **Material**	Yes	Yes	Substantially Equivalent
• **Product Characteristics**	Yes	Yes	Substantially Equivalent
• **Size**	Yes	Yes	Substantially Equivalent
• **Manufacturer Name and Address**	Yes	Yes	Substantially Equivalent
• **Single Use Only**	Yes	Yes	Substantially Equivalent
• **In Pairs, Left/Right**	Yes	Yes	Substantially Equivalent

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

• **Country of Manufacturing**	Yes	Yes	Substantially Equivalent
• **List of Chemotherapy Drugs and Breakthrough Times**	Yes	Yes	Substantially Equivalent

Summary of Non-Clinical Testing

The biocompatibility evaluation for the SensiCare PI Surgical Glove was conducted in accordance with ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA. The SensiCare PI Surgical Gloves are classified as a surface contacting device with a limited contact duration of less than 24 hours.

The following tests were performed to evaluate the biocompatibility of the SensiCare PI Surgical Gloves:

- ISO 10993-10: Irritation – Intracutaneous reactivity
- ISO 10993-10: Delayed-Type Hypersensitivity (Sensitization) – Guinea Pig Maximization Test

Performance Testing (Bench)

Permeation testing was conducted on the SensiCare PI Surgical Glove per ASTM D6978-05, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. The gloves were tested against fifteen chemotherapy drugs.

Physical performance qualities were evaluated per ASTM D3577, Standard Specification for Rubber Surgical Gloves.

Summary of Clinical Testing

This section does not apply. No clinical testing was performed.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the SensiCare PI Surgical Glove is as safe and as effective and performs as well as the predicate, Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs (K110272). Therefore, the SensiCare PI Surgical Glove is substantially equivalent to the predicate.