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 22, 2016

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

Re: K151754
Trade/Device Name: Glide-On Vinyl Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: February 22, 2016
Received: February 23, 2016

Dear Ms. 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 and Part 809); 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 and Part 809), 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.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
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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)*
K151754

Device Name
Glide-On Vinyl Examination Gloves

Indications for Use *(Describe)*
The Glide-On Vinyl Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

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.

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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 21, 2016

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Glide-On Vinyl Examination Gloves
Proprietary Name: Glide-On Vinyl Examination Gloves
Common Name: Vinyl Patient Examination Glove
Classification Name: Patient Examination Glove
Product Code: LYZ
Product Class: Class I
Regulation #: 21 CFR 880.6250
Classification Panel: General Hospital

Predicate Device
Powder-Free PVC Vinyl Patient Examination Glove, Clear (non-colored)
K142703

Device Description
The Glide-On Vinyl Examination Gloves are single use only, disposable gloves intended for medical purposes to be worn on the hands or fingers of examiners. The gloves are powder-free and are made of poly

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vinyl chloride (PVC) with an inner coating of polyurethane. This inner polyurethane coating acts as a lubricant to aid in the donning of the gloves when hands are wet, damp or dry. The gloves are offered non-sterile and are available in small, medium, large and extra large sizes.

Indications for Use

The Glide-On Vinyl Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

Summary of Technological Characteristics

The Glide-On Vinyl Examination Gloves are substantially equivalent to the predicate, K142703. Both gloves have the same intended use, same material and the same device performance.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Glide-On Vinyl Examination Gloves	Powder-free PVC Vinyl Exam Gloves	N/A
510(k) Reference		K142703	N/A
Product Owner	Medline Industries, Inc	Hebei Grandeast Plastic Products Co., Ltd.	Different
Product Code	LYZ	LYZ	Same
Intended Use	The Glide-On Vinyl Examination Gloves are disposable device intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	The powder-free PVC vinyl exam gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Sizes	Small Medium Large Extra-Large	Small Medium Large Extra-Large	Same
Materials	PVC Lubricant – Polyurethane with a viscosity up to 18 centipoise	PVC Lubricant – Polyurethane with a viscosity up to 4.6 centipoise	Similar
Dimensions - Length	Complies with ASTM D5250-06 (reapproved	Complies with ASTM D5250-06 (reapproved	Same

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	2011) ≥230mm	2011) ≥230mm	
Dimensions - Width	Complies with ASTM D5250-06 (reapproved 2011) Small - 85±5mm Medium - 95±5mm Large - 105±5mm Extra Large - 115±5mm	Complies with ASTM D5250-06 (reapproved 2011) Small - 85±5mm Medium - 95±5mm Large - 105±5mm Extra Large - 115±5mm	Same
Dimensions - Thickness	Complies with ASTM D5250-06 (reapproved 2011) Palm – 0.10±0.02mm Finger – 0.10±0.02mm	Complies with ASTM D5250-06 (reapproved 2011) Palm – 0.10±0.02mm Finger – 0.10±0.02mm	Same
Physical Properties	Complies with ASTM D5250-06 (reapproved 2011) Before Aging/After Aging Tensile Strength ≥11MPa Ultimate Elongation ≥300%	Complies with ASTM D5250-06 (reapproved 2011) Before Aging/After Aging Tensile Strength ≥11MPa Ultimate Elongation ≥300%	Same
Freedom from Holes	Complies with ASTM D5250-06 (reapproved 2011) and ASTM D5151-06 (reapproved 2011) G-1, AQL 2.5	Complies with ASTM D5250-06 (reapproved 2011) and ASTM D5151-06 (reapproved 2011) G-1, AQL 2.5	Same
Powder or Powder-free	Powder-free	Powder-free	Same
Residual Powder	Complies with ASTM D5250-06 (reapproved 2011) <2mg per glove	Complies with ASTM D5250-06 (reapproved 2011) <2mg per glove	Same
Colorant	No colorant used	No colorant used	Same
Sterile or Non-sterile	Non-sterile	Non-sterile	Same

Summary of Non-Clinical Testing

The biocompatibility evaluation for the Glide-On Vinyl Examination Gloves 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 Glide-On Vinyl Examination 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 Glide-On Vinyl Examination Glove:

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

An evaluation was performed comparing the frictional properties of the Glide-On Vinyl Examination Gloves to a plain vinyl glove. The testing was performed per ASTM D1894, Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting. Both gloves were tested under wet and dry conditions.

A user study involving one hundred seventy (170) subjects was also performed to evaluate the ease of glove donning on damp hands and dry hands compared to three other vinyl gloves coated with polyurethane. The study evaluated the amount of time it took each user to don each glove and also the amount of glove tears that occurred during the donning of each glove.

Summary of Clinical Testing

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

Conclusion

Based on the non-clinical performance testing Medline Industries, Inc. concludes that the Glide-On Vinyl Examination Gloves are substantially equivalent to the predicate, Powder-free PVC Vinyl Exam Gloves (K142703).