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

January 9, 2015

Medline Industries, Inc.
Matt Clausen
Sr. Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

Re: K142635
Trade/Device Name: Medline Silicone Foley Catheters
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: December 10, 2014
Received: December 15, 2014

Dear Matt Clausen,

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,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K142635

Device Name
Medline silicone Foley catheters

Indications for Use *(Describe)*
Medline silicone Foley catheters are intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation.

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:

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 60060-4486

510(k) Summary (as required per 21 CFR 807.92)

Summary Preparation Date

September 10, 2014

Submitter / 510(k) Sponsor

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

Contact Person

Matt Clausen
Sr. Regulatory Affairs specialist
Phone: 847-643-4785
Fax: 847-643-4482

Device Name / Classification

Device Name: Silicone Foley Catheter
Proprietary Name: Medline Silicone Foley Catheter
Common Name: Foley Catheter
Classification Name: Urological catheter and accessories (21 CRF 876.5130, product code – EZL)

Predicate Device

Well Lead silicone and latex catheters, K082815

Device Description

Medline silicone Foley catheters are two-way Foley catheters which are placed in the bladder through the urethra. The urine drains out through the catheter into a collection device attached to the catheter. Three-way Foley catheters offer the option of irrigating the bladder through a 3rd lumen. These catheters have various balloon volumes, shaft sizes and irrigation features.

Indications for Use

Medline silicone Foley catheters are intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation.

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060-4486

Summary of Technological Characteristics

Information within this Premarket Notification demonstrates that there are no significant differences in technological characteristics between Medline's silicone Foley catheters and the cited predicate device.

Summary of Non-Clinical Testing

The safety and effectiveness of Medline's silicone Foley catheters is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification. Functional performance testing of the Medline silicone Foley catheter demonstrated device effectiveness in accordance with relevant ASTM F623 test methods.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline silicone Foley catheter is safe, effective and substantially equivalent as described herein.