June 12, 2019

Medline Industries, Inc.
Dinah Rincones
Regulatory Specialist
Three Lakes Drive
Northfield, IL 60093

Re: K183335
Trade/Device Name: Medline Poly-Cath Red Polymer Urethral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: May 2, 2019
Received: May 6, 2019

Dear Dinah Rincones:

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,

for Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*

K183335

Device Name
Medline Poly-Cath Red Polymer Urethral Catheter

Indications for Use *(Describe)*
Medline Poly-Cath Red Polymer Urethral Catheter is intended for use in the drainage of urine from the bladder, and it is indicated for the intermittent catheterization of male and female adults who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.

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

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Dinah Rincones
Regulatory Affairs Specialist
Phone: 847-949-2687
Email: DRincones@medline.com

Summary Preparation Date
November 30, 2018

Type of 510(k) Submission
Traditional

Device Name / Classification
- Trade Name: Medline Poly-Cath™ Red Polymer Urethral Catheter
- Device Common Name: Catheter, Urethral
- Regulation Name: Urological Catheter and Accessories
- Regulation Number : 21 CFR §876.5130
- Product Code: GBM
- Device Class: Class II
- Review Panel: Gastroenterology/Urology

Predicate Device DOVER
ROB-NEL Catheter K040897

Device Description
Medline Poly-Cath™ Red Polymer Urethral Catheter is a single use, flexible, straight urinary catheter that is inserted through the urethra into the bladder allowing urine to drain. The proposed device is comprised of a polyvinyl chloride (PVC) compound that does not contain bis (2-ethylhexyl) phthalate

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(DEHP). The catheter has a rounded closed tip with two oval drainage eyes at one end, and a funnel bonded to the opposite end. Medline Poly-Cath™ Red Polymer Urethral Catheter is provided sterile.

Indications for Use

Medline Poly-Cath Red Polymer Urethral Catheter is intended for use in the drainage of urine from the bladder, and it is indicated for the intermittent catheterization of male and female adults who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.

Summary of Technological Characteristics

The Medline Poly-Cath™ Red Polymer Urethral Catheter is similar in design, indications for use and technological characteristics to the predicate device cleared under K040897, DOVER® ROB-NEL Catheter.

TABLE 1 – Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Poly-Cath™ Red Polymer Urethral Catheter	DOVER® ROB-NEL Catheter	**N/A**
510(k) Reference	N/A	K040897	**N/A**
Product Owner	Medline Industries, Inc.	Covidien	**N/A**
Intended Use	Medline Poly-Cath Red Polymer Urethral Catheter is intended for intermittent catheterization to drain urine from the urinary bladder. The product is intended for use on patients who are not capable of voluntary urination.	DOVER® ROB-NEL Catheter is intended for intermittent catheterization to drain urine from the urinary bladder. The product is intended for use on patients who are not capable of voluntary urination.	**Same**
Indications for Use	Medline Poly-Cath Red Polymer Urethral Catheter is intended for use in the drainage of urine from the bladder, and it is indicated for the intermittent catheterization of male and female adults who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.	The proposed device is intended for use in the drainage of urine from the urinary bladder. The product is intended for intermittent catheterization on patients who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.	**Similar**
Design Features	Flexible, straight catheter with two staggered eyes, a rounded closed tip and a funnel end.	Flexible, straight catheter with two staggered holes, a rounded closed tip and a funnel end.	**Same**

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Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Design Configurations	One size: 16", 14 Fr	Various sizes, including 16" , 14 Fr	**Similar**
Materials	PVC, colorants, adhesive	PVC, colorants	**Similar**
Prescription vs. OTC	Prescription	Prescription	**Same**
Biocompatibility, Contact Duration	ISO 10993-1, Limited Contact (<24h)	ISO 10993-1, Limited Contact (<24h)	**Same**
Performance Testing	Conforms to applicable standard specification for urethral catheters	Conforms to applicable standard specification for urethral catheters	**Same**
Sterile vs. Non-Sterile	Sterile	Sterile	**Same**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same**
Single Use vs. Reusable	Single Use	Single Use	**Same**

Summary of Non-Clinical Testing

Non-clinical verification of The Medline Poly-Cath™ Red Polymer Urethral Catheter has been conducted to evaluate its safety, performance and functionality. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination. Specifically, the proposed device has been evaluated through the following tests:

Biocompatibility Testing

The biocompatibility evaluation 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 following tests were performed to evaluate the biocompatibility of Medline Poly-Cath™ Red Polymer Urethral Catheter:

- **Cytotoxicity:** ISO MEM Elution (GLP) – in accordance with ISO 10993-5:2009 "Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity".
- **Sensitization:** ISO Guinea Pig Maximization Sensitization Test (GLP) - in accordance with the test guidelines described in ISO 10993-10: 2010 Standard, "Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Sensitization".
- **Irritation:** ISO Vaginal Irritation Study in Rabbits (GLP) - in accordance with the test guidelines described in ISO 10993-10: 2010 Standard, "Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Sensitization".

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- **Acute Systemic Toxicity:** ISO Systemic Toxicity Study in Mice (GLP) - in accordance with the test guidelines described in ISO 10993-11: 2006 Standard, "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity".

Performance Testing (Bench)

Functional performance testing was carried out on the final finished form of the proposed device. The table below provides a summary of all functional testing performed.

TABLE 1 - Summary of Performance Testing

Test Objective	Testing Standards	Performance Results
Catheter Surface Finish	BS EN 1616:1997	Meet BS EN 1616:1997 § 4.2 Requirements
Catheter Dimensional Analysis	BS EN 1616:1997	Meet BS EN 1616:1997 § 4.3 Requirements
Catheter Strength	BS EN 1616:1997	Meet BS EN 1616:1997 § 4.4 Requirements
Catheter Flow Rate	BS EN 1616:1997 BS EN 1618:1997	Meet BS EN 1616:1997 § 4.8 Requirements and BS EN 1618:1997 § Annex E
Connector Security	BS EN 1616:1997	Meet BS EN 1616:1997 § 4.5 Requirements

Additional Non-Clinical Evaluations

- Stability (Shelf-Life) Testing.
- Ethylene Oxide Sterilization Residuals Evaluation.
- Bioburden Evaluation.
- Simulated Shipping Testing.
- Packaging Integrity Testing.

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Conclusion

In accordance with 21 CFR Part 807, and based on a comparison of 'Indications for Use,' technological characteristics and performance data, Medline Industries, Inc. concludes that the proposed Medline Poly-Cath™ Red Polymer Urethral Catheter is substantially equivalent to the predicate device, DOVER ROB-NEL Catheter (K040897).