February 22, 2018

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

Re: K172541
Trade/Device Name: Medline Catheter Specimen Collector
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: December 28, 2017
Received: January 2, 2018

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*
K172541

Device Name
Medline Catheter Specimen Collector

Indications for Use *(Describe)*
Medline Catheter Specimen Collector is a tubular device that is inserted through the urethra and utilized for passage of fluids from the urinary tract.

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)]

Summary Preparation Date
August 21, 2017

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

Submission Correspondent
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Type of 510(k) Submission
Traditional

Device Name / Classification
Device Common Name – Catheter, Straight
Proprietary Name – Medline Catheter Specimen Collector
Classification – Class II
Panel – Gastroenterology / Urology
Product Code – EZD
Regulation # – 21 CFR 876.5130 Urological Catheter and Accessories

Predicate Device
Busse Hospital Disposable Urethral Catheter (K041464)

Indications for Use
Medline Catheter Specimen Collector is a tubular device that is inserted through the urethra and utilized for passage of fluids from the urinary tract.

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Device Description

The Medline Catheter Specimen Collector is a sterile, single-use device consisting of a straight polyvinyl chloride (PVC) tube that is inserted through the urethra and utilized for passage of fluids from the urinary tract directly into a collection container. It is intended to be used in urinary collection procedures as a way to obtain a urine sample through a catheter inserted through the urethra into the bladder. The sample is obtained by this method to avoid contamination from the urethra, or if urine cannot be obtained from the patient using the clean catch method.

The Medline Catheter Specimen Collector includes a straight urethral catheter, a sheath to protect the catheter during shipping, a pre-attached collection container, and a cap. The catheter is made of polyvinyl chloride (PVC) and features a closed rounded tip with four (4) drainage eyelets. It is available in a combination of French sizes (5FR and 8FR) and lengths ranging from 6.5 to 14 inches.

Summary of Technological Characteristics

The Medline Catheter Specimen Collector is similar in design, intended use, function and technological characteristics to the predicate device cleared under K041464, Busse Hospital Disposable Urethral Catheter.

TABLE 1: Comparison of proposed and predicate device

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Catheter Specimen Collector	Busse Hospital Disposable Urethral Catheter	Different
510(k) Reference	TBD	K041464	Different
Product Owner	Medline Industries, Inc.	Busse Hoapital Disposables, Inc.	Different
Product Code	EZD	EZD	Same
Intended Use	The Medline Catheter Specimen Collector is a tubular device that is inserted through the urethra and utilized for passage of fluids from the urinary tract.	The Busse Hospital Disposable Urethral Catheter is a tubular device that is inserted through the urethra and utilized for passage of fluids from or to the urinary tract.	Same
Description	The device is used in urinary collection procedures as a way to obtain a urine sample. The urine is obtained by this method to avoid contamination from the urethra, or if urine cannot be obtained from the patient using the clean catch method.	The device is used in urinary collection procedures as a way to obtain a urine sample. The urine is obtained by this method to avoid contamination from the urethra, or if urine cannot be obtained from the patient using the clean catch method.	Same

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Regulation Number	21 CFR 876.5130	21 CFR 876.5130	Same
Design Feature – Catheter Sizes	Available in 5FR and 8FR designs	Available in 5FR and 8FR designs	Same
Design Feature – Drainage Eyes	Tip features 4 drainage eyes	Tip features 2 or 3drainage eyes	Similar
Catheter Material	Clear PVC	Clear PVC	Same
Packaging	Heat-sealed in soft pouch with Tyvek lid	Heat-sealed in soft pouch with Tyvek lid	Same
Performance Specifications	Conforms to recognized standard for urethral catheters	Conforms to recognized standard for urethral catheters	Same
Prescription vs. OTC	Prescription	Prescription	Same
Contact Duration	Limited (≤ 24 h)	Limited (≤ 24 h)	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Summary of Non-Clinical Testing

Non-clinical verification of The Medline Catheter Specimen Collector 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:
  - Cytotoxicity – MEM Elution per ISO 10993-5
  - Sensitization – Guinea Pig Maximization Test per ISO 10993-10
  - Irritation – Intracutaneous Reactivity per ISO 10993-10
- Functional Performance Testing:
  - Catheter Surface Finish per BS EN 1616:1997 §4.2
  - Catheter Dimensions per BS EN 1616:1997 §4.3
  - Catheter Strength per BS EN 1616:1997 §Annex A
  - Catheter Flow Rate per BS EN 1616:1997 §Annex E

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- Additional Non-Clinical Evaluations:
  - Bioburden Testing
  - Package Seal Integrity per ASTM F1929
  - Stability (Shelf-Life) Testing
  - Ethylene Oxide and Ethylene Chlorohydrin Residual Evaluation Studies
  - Internal Risk Analysis

Summary of Clinical Testing

Not applicable.

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 Catheter Specimen Collector is substantially equivalent to the predicate device, Busse Hospital Disposable Urethral Catheter (K041464).