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 7, 2016

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

Re: K150731
Trade/Device Name: Medline Epidural Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: October 27, 2015
Received: October 30, 2015

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" (21CFR 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 I. Keith, M.S.
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Division of Anesthesiology,
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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)*
K150731

Device Name
Medline Epidural Catheter

Indications for Use *(Describe)*
The Medline Epidural Catheter is indicated for the injection of local anesthetics into the epidural space for patients over 22 lbs. (10kgs.), for a duration of use of up to 72 hours.

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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Medline Industries, Inc.
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Mundelein, IL 60060-4486

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

Summary Preparation Date

March 4, 2016

Submitter / 510(k) Sponsor

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

Contact Person

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Sr. Regulatory Affairs specialist
Phone: 847-643-4785
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Device Name / Classification

Device Name: Epidural Catheter
Proprietary Name: Medline Epidural Catheter
Common Name: Epidural Catheter or Anesthesia Conduction Catheter
Classification Name: Catheter, Conduction, Anesthetic (21 CFR 868.5120, product code – BSO)

Predicate Device

B. BRAUN MEDICAL, INC. - PERIFIX CATHETER AND CONTIPLEX CATHETER, K042488

Device Description

The Medline Epidural Catheter is a single use device made of flexible, nylon tubing which is sold as sterile individually packaged and sterile packaged inside a kit/procedure tray. The epidural catheter is designed as a closed tip device with 3 eyes for distribution of anesthetic agents. The catheters have a black radiopaque stripe. The catheter is available in 19G and 20G and is 800 millimeters long. The catheter has a marked tip, with 1cm increments up to 25cm. The 10cm mark is indicated by two marks, 15cm by three marks, 20cm by four marks and 25cm by five marks. As an added safety feature, the solid wide warning mark indicates exit of catheter from needle when using a Medline Epidural Needle. This device is intended to be used in conjunction with an epidural catheter connector cleared under K051171.

Indications for Use

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The Medline Epidural Catheter is indicated for the injection of local anesthetics into the epidural space for patients over 22 lbs. (10kgs.), for a duration of use of up to 72 hours.

Summary of Technological Characteristics

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

A summary of the technological characteristics of this subject device compared to the predicate device is provided below.

Attribute	Subject Device	Predicate Device	Comparison
Product	Medline's Epidural Catheter	PERIFIX CATHETER AND CONTIPLEX CATHETER	n/a
510(k)	To be assigned	K042488	n/a
Intended Use	The Medline Epidural Catheter is indicated for the injection of local anesthetics into the epidural space for patients over 22 lbs. (10kgs.)	The B. Braun Regional Anesthesia Catheter is a device intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management during the pre-operative, perioperative and postoperative periods associated with general and orthopedic surgery as well as labor and delivery. Routes of administration include epidural and perineural (peripheral nerve block).	Same
Usage	Prescription use only	Prescription use only	Same
Materials	Polymer nylon	Polyamide/polyurethane	Similar
How supplied	Sterile	Sterile	Same
Diameter	19 and 20 gauge	19 and 20 gauge	Same
Length	800 millimeters	400-1010 millimeters	Similar
Type	Closed tip / 3 eyelits	Closed, open tips / 3-6 eyelits	Similar
Catheter markings	1-5 rings (black ink)	1-4 rings (blue ink)	Similar

Based on the differences in the table above the following tests were performed to mitigate risks:

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Summary of Non-Clinical Testing

The substantial equivalence of Medline's Epidural Catheter is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification. Functional performance testing of the Medline Epidural Catheter demonstrates device substantial equivalence in accordance with relevant test methods.

Standard or Reference	Test Method	Data Generated	Test Result
ISO 109993-5	Cytotoxicity	Cytotoxicity	Pass
ISO 109993-10	Intracutaneous reactivity	Dermal irritation	Pass
ISO 109993-10	Maximization sensitization	Dermal sensitization	Pass
ISO 109993-11	Subacute toxicity	Subacute toxicity	Pass
ISO 109993-11	Systemic injection	Systemic injection	Pass
ASTM F 756-13	Hemolysis assay	Hemolytic potential	Pass
USP Pyrogen Test Procedure, Section <151> (USP37)	Pyrogen	Non-pyrogenic	Pass
ASTM F 623	Flow rate	Flow rate	Pass
	Extractables analysis	Extractables analysis	No toxicological risk
	Appearance / ink / x-ray detection	Visual appearance / ink tenacity / x-ray detection	Pass
	Tensile strength	Tensile properties	Pass
	Particulate matter	Particulate size	Pass
	Kink / dimensional analysis testing	Flow rate / marking accuracy	Pass

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 Epidural Catheter is as safe, as effective and substantially equivalent to the predicate device [K042488] as described herein.