Medline Industries, Inc.
Claire Pigman
Associate Manager
Three Lakes Drive
Northfield, Illinois 60093

Re: K181782
Trade/Device Name: Medline Reinforced Epidural Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: January 28, 2019
Received: January 29, 2019

Dear Claire Pigman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Todd D. Courtney
-S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181782

Device Name
Medline Reinforced Epidural Catheter

Indications for Use *(Describe)*
The Medline Reinforced Epidural Catheter is indicated for the injection of local anesthetics into the epidural space for patients over 22lbs. (10kg), for a duration of use 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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# K181782 - 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

## Submission Correspondent(s)

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## Summary Preparation Date

June 29, 2018
(Updated January 28, 2019)

## Type of Submission

Traditional 510(k)

## Device Name / Classification

Proprietary Name: Medline Reinforced Epidural Catheter
Classification Name: Catheter, Conduction, Anesthetic
Product Code: BSO
Classification Panel: Anesthesiology

Medline Industries, Inc.
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Regulatory Class: Class II
Regulation Number: 21 CFR 868.5120

## Predicate Device

Predicate Device Name: ARROW® FlexTip Plus® Epidural Catheter
Predicate Device 510(k) Number: K140110
Predicate Device Indications for Use: The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.

## Device Description

The Medline Reinforced Epidural Catheter is a single use device made of flexible polyurethane elastomer tubing. The subject device is sold sterile, and will be packaged inside of a convenience kit alongside a variety of other components that are outside the scope of this 510(k) submission. The proposed epidural catheter is designed as a closed tip device with two eyelets to provide for the dispersion of anesthetic agents. The catheter features a 19G design and is 913 millimeters (mm) long. The catheter has a marked tip, with 10mm increments up the length of the device (up to 913mm). The 100mm mark is indicated by two marks, 150mm by three marks, 200mm by 4 marks, and 250mm by 5 marks. In addition, the Medline Reinforced Epidural Catheter has an internal radiopaque inner spring that is evenly distributed inside the device, terminating 2+/-0.05mm from the liquid outlet end. As an added safety feature, a solid wide warning mark is featured on the proposed device to indicate exit of the catheter from a needle when used in conjunction with an epidural needle. The proposed Medline Reinforced Epidural Catheter will be available in the following design configuration:

| Medline Item Number | Description | Gauge | Length |
|---|---|---|---|
| REPICATH19 | Medline Reinforced Epidural Catheter | 19G | 913mm |

Epidural catheters, like the proposed and predicate devices, are used during epidural administration procedures to allow for administration of local anesthetic medications into the epidural space of a patient. Epidural administration in general is a medical route of administration in which a drug, such as an epidural anesthetic, is injected into a patient's epidural space around the spinal cord. Though the epidural route is frequently employed by trained practitioners (i.e. physicians and nurse anesthetists) to administer anesthetic agents for patient pain relief, it is a procedure that is only performed by skilled healthcare personnel that are trained to be well-versed in anatomical landmarks, safe technique, and potential complications. The epidural technique employed during epidural administration procedures most commonly involve the injection of drugs through a catheter, like the proposed and predicate devices, that are placed into the epidural space. A high-level overview describing when these devices are used, how they are used, and by whom, is provided below.

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*Principle of Operation:* Following puncture and verification of the epidural space with an epidural needle, the distal tip of an epidural catheter is introduced through the epidural needle. To facilitate this process, the Threading Assist Device that is included with the proposed and predicate devices is used to attach to the hub of the epidural needle to aid in inserting the catheter. The catheter is then advanced the desired distance into the epidural space, as noted by the millimeter markings provided on the catheter. After the catheter has been advanced to the desired distance (not more than 5 cm), it is held in place while the needle is removed over it. As such, the catheter's position is maintained and will often be secured to the skin with adhesive tape to ensure it remains undisturbed per internal hospital protocols. The proximal end of the catheter can then be attached and inserted into the catheter connector, which is also provided with the proposed and predicate devices, to facilitate its connection to a syringe so that anesthetics may be injected through the catheter and ultimately into the epidural space.

*Proposed Conditions of Use:* Injecting medication into a patient's epidural space is primarily performed for analgesia and the proposed device is intended to be used during epidural medication administration on patients over 22 lbs. that require administration of local anesthetics. When the proposed device is advanced into the epidural space, it can remain in place for up to 72 hours, which allows for epidural medication administration to be continued post-operatively (and re-dosed intraoperatively) if needed. Epidural administration procedures are carried out by trained healthcare practitioners in accordance with a particular healthcare institution's internal procedures, as well as current medical practice guidelines. Epidural medication administration is most commonly used alone for analgesia to provide pain relief anywhere in a patient's lower body and as high as the chest, and is frequently employed during childbirth and for post-operative analgesia after an operation. However, a practitioner may also utilize it for an adjunct to general anesthesia during a wide variety of surgery, for example gynecological surgery (e.g. hysterectomy), orthopedic surgery (e.g. hip replacement), general surgery (e.g. laparotomy) and vascular surgery (e.g. open aortic aneurysm repair). Additionally, epidural administration procedures are also performed as a sole technique for surgical anesthesia, most frequently in Caesarean sections, for example, which can allow the patient to remain awake during the operation.

*Anatomical Location of Use and Description of Users: The* proposed device will be used during epidural administration procedures to allow for administration of local anesthetic medications into the epidural space of a patient. The epidural space is the area between the dura mater and the vertebral wall, containing fat and small blood vessels. Also in contact with the inner surface of the dura is another membrane called the arachnoid mater ("arachnoid"), which is the membrane that contains the cerebrospinal fluid surrounding the spinal cord. Therefore, epidural administration procedures, which involve inserting and threading an epidural needle between the bone, through the ligaments, and into the epidural space, are required to be performed only by trained and technically proficient healthcare practitioners, as great care needs to be taken to avoid puncturing the layer immediately below containing CSF. The level of the spine at which the catheter is best placed is dictated by the practitioner performing the procedure and depends mainly on the site and type of intended operation or the anatomical origin of pain. After placement of the tip of the needle into the epidural space, an epidural catheter, like the proposed device, is threaded approximately 3 to 4 centimeters through the needle. The needle is then withdrawn over the catheter.

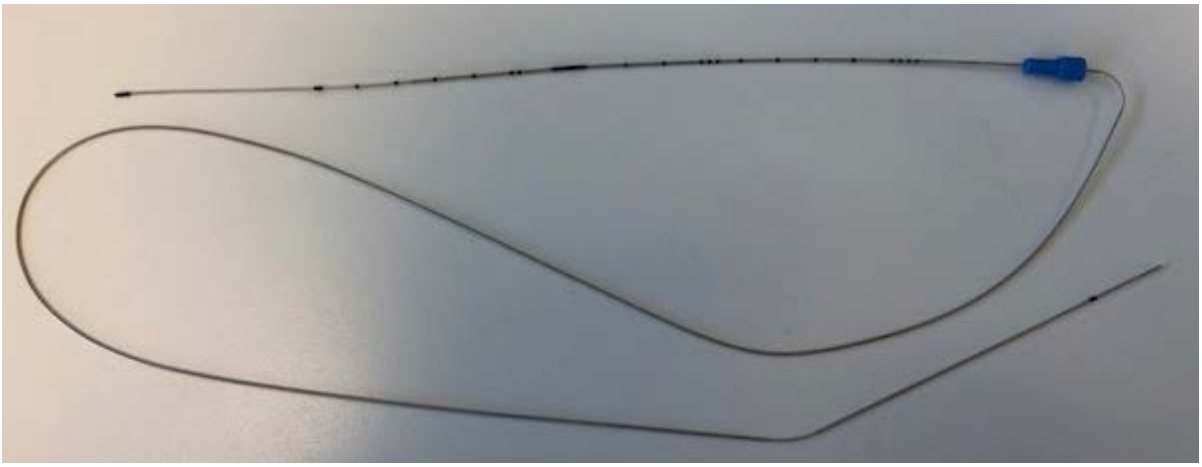
**Medline Industries, Inc.**
Three Lakes Drive
Northfield, IL 60093

Generally, while the catheter's placement is being maintained, it will be secured to a patient's skin with adhesive tape to prevent it from becoming dislodged.

Please refer to Figure 1 and Figure 2 for photographs of the proposed device.

**Figure 1: Medline Reinforced Epidural Catheter (Photograph 1 of 2)**

**Figure 2: Medline Reinforced Epidural Catheter (Photograph 2 of 2)**



## Indications for Use

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

## Summary of Technological Characteristics

Table 1 on the following page provides a side-by-side comparison between the proposed device, the Medline Reinforced Epidural Cather, and the predicate device, the ARROW® Flextip Plus® Epidural Catheter (K140110).

**Table 1: Comparison of Proposed and Predicate Devices**

| Device Characteristic | Proposed Device | Predicate Device | Comparison Analysis |
|---|---|---|---|
| **Product Name** | Medline Reinforced Epidural Catheter | ARROW® FlexTip Plus® Epidural Catheters | N/A |
| **510(k) Reference** | TBD | K140110 | N/A |
| **Product Owner** | Medline Industries, Inc. | Teleflex | N/A |
| **Product Code** | BSO | BSO | Same |
| **Intended Use** | Indicated for the injection of local anesthetics into the epidural space for patients over 22lbs. (10kg), for duration of use up to 72 hours. | Permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours. | Same |
| **Regulation Number** | 21 CFR 868.5120 | 21 CFR 868.5120 | Same |
| **Design Features** | Single lumen<br>Internal radiopaque reinforced coiled wire<br>Closed tip design – 2 ports | Single lumen<br>Internal radiopaque reinforced coiled wire<br>Available in open or closed tip design | Similar |
| **Materials** | Polyurethane Tubing | Polyurethane Tubing | Same |
| **Available in Sterile Kit Configurations** | Yes | Yes | Same |
| **Dimensions** | 19G x 913mm | 19G x 900mm | Similar |
| **Prescription vs. OTC** | Prescription Use Only | Prescription Use Only | Same |
| **Contact Type and Duration** | Externally communicating/<br>Contact-blood path, indirect /<br>Duration: prolonged use (>24 hours <30days). | Externally communicating/<br>Contact-blood path, indirect /<br>Duration: prolonged use (>24 hours <30days). | Same |
| **Patient Population** | Adult (patients weighing over 10kg) | Adult | Same |
| **Sterile vs. Non-Sterile** | Sterile | Sterile | Same |
| **Sterilization Method** | Ethylene Oxide (EO) | Ethylene Oxide (EO) | Same |
| **Disposable vs. Non-Disposable** | Disposable | Disposable | Same |
| **Single Use vs. Reusable** | Single Use | Single Use | Same |
| **“MR Conditional” Claim** | No | Yes | Different |
| **Non-pyrogenic Claim** | Yes (use for fluid pathway contacting components) | Yes | Similar |
| **Shelf Life** | 1 year | Not indicated | N/A |

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## Shelf Life and Sterilization

The proposed Medline Reinforced Epidural Catheter is terminally sterilized by Ethylene Oxide (EO). The sterilization validation for the proposed device has been conducted in accordance with ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*, to ensure a Sterility Assurance Level (SAL) of 1 x $10^{-6}$. The proposed device has also been evaluated for EO and Ethylene Chlorohydrin (ECH) residuals in accordance with ISO 10993-7:2008(R)2012, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.*

Additionally, in accordance with ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, aging studies have been conducted to verify a one-year shelf life of the subject device and ensure that its functionality and sterility are successfully maintained throughout the duration of this shelf life. For additional information on the sterilization and shelf life of the proposed device, please refer to Section 14 of this submission.

## Summary of Non-Clinical Testing

Non-clinical verification of the Medline Reinforced Epidural 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 its effectiveness in accordance with relevant test methods, and ultimately support a substantial equivalence determination. Particularly, chemical, safety, and functional performance testing of the Medline Reinforced Epidural Catheter were conducted to adequately demonstrate the effectiveness of this device in accordance with relevant test methods cited below:

*Chemical Safety Testing*

- Particulate Matter Testing in accordance with USP <788> *Particulate Matter Injections*
- Limulus Amebocyte Lysate (LAL) Bacterial Endotoxin Testing in accordance with USP <85> Bacterial Endotoxin Testing

*Functional Performance Testing*

- Kink Testing
- Dimensional Analysis
- Simulated Distribution Testing in accordance with ISTA 3A-2018 *General Simulation Performance Test Procedure for Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less*
- Transportation Testing in accordance with ASTM D4169-16 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- Visual Appearance Testing
- Ink Adherence Testing
- Tensile Strength Testing in accordance with ASTM D412-16 *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension**

**Medline Industries, Inc.**
Three Lakes Drive
Northfield, IL 60093

- Flow Rate Testing in accordance with ASTM F623-99 *Standard Performance Specification for Foley Catheter (Flow Rate)**
- Connector Pull Out Testing
- Leakage Testing in accordance with ISO 80369-6 *Small-bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications***
- Packaging Integrity Testing in accordance with ASTM F1929-15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- Seal Strength Testing in accordance with ASTM F88-16 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- X-Ray Opaque Detection Testing

Additional information regarding the performance testing described above is located in Section 18 of this submission. In addition, full performance testing reports for the Medline Reinforced Epidural Catheter can be found in Appendix F.

The biocompatibility evaluation for the Medline Reinforced Epidural Catheter 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 proposed device is classified as an externally communicating device that comes in indirect contact with the blood path for a prolonged duration of use (>24 hours, <30days). The following biocompatibility tests were performed:

- Cytotoxicity – ISO 10993-5:2009 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity*
- Sensitization – ISO 10993-10: 2010 *Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization*
- Irritation – ISO 10993-10 2010 *Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization*
- Acute Systemic Toxicity – ISO 10993-11: 2017 ISO 10993-11: 2017 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Material-Mediated Pyrogenicity – USP <151> *Pyrogen Test* as recommended in ISO 10993-11:2006 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Hemolysis – ASTM F756, *Standard Practice for Assessment of Hemolytic Properties of Materials* and ISO 10993-Part 4:2017 *Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood*
- Subacute Systemic Toxicity-- ISO 10993-11: 2006 *Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity*
- Chemical Characterization – ISO 10993-18:2005 *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*

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Final biocompatibility test protocols and reports are available for the Agency's review in Appendix E.

## Summary of Clinical Testing

Not applicable. No clinical testing was conducted on the proposed device.

## 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 Reinforced Epidural Catheter (i.e. REPICATH19) is substantially equivalent to the predicate device, ARROW® FlexTip Plus® Epidural Catheters (K140110).