K133316

MAY 2 8 2014

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510(k) Summary

Submitter Information:

Name: Epimed International, Inc.
Address: 141 Sal Landrio Drive
Crossroads Business Park
Johnstown, N.Y. 12095

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Contact Person: Preston H. Frasier
Manager – QA/RA
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Date Prepared: October 23rd, 2013

Device Name & Classification:

Device Trade Name: Spirol® Block Continuous Peripheral Nerve Block Catheter

Common Name: Peripheral Nerve Block Catheter

Classification Name: Anesthesia Conduction Catheter, BSO (21 CFR 868.5120)

Predicate Device(s) Information:

Predicate Device #1: Epimed International's "Feth-R-Kath" (K981329)
- Catheter later renamed "Spirol®" by Epimed.

Predicate Device #2: Arrow International's "ARROW FlexBlock Continuous Peripheral Nerve Block Catheter" (K122027)

Device Description:

Epimed's Spirol® Block Continuous Peripheral Nerve Block Catheter has the following characteristics:

- 19 Ga. & 20 Ga., 14" to 24" in length.
- Offered in open and closed end distal tip configurations.
- Offered in styletted and non-styletted versions.
- Internal radiopaque, echogenic coiled reinforced wire to allow visibility under fluoroscopy and/or ultrasound.
- Catheters to be provided in sterile kit/set style configurations or as a standalone replacement catheter.

Statement of Intended Use:

The catheter is designed to deliver anesthesia to manage perioperative pain and/or alleviate postoperative analgesia.

Statement of Indications For Use:

The Spirol® Block Continuous Peripheral Nerve Block Catheter permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques including upper extremity, lower extremity, abdominal and paravertebral locations for periods not exceeding 72 hours.

Technological Characteristics and Substantial Equivalence:

Epimed's Spirol® Block Continuous Peripheral Nerve Block Catheter has identical Intended Use and Indications For Use as that of the Predicate Device #2 (K122027). The catheter itself is identical in design, manufacture and material composition to Predicate Device #1 (K981329).

The catheter is a single-use, disposable device consisting of a polymer coated stainless steel spring. The catheter is available in various lengths, as well as open-ended or closed-ended configurations; the closed-ended models having three eyes (injection ports) at the distal end. The Spirol® Block is also available in styletted or non-styletted versions, as well as 19 Ga. or 20 Ga. models. This catheter is identical in design, manufacture, and material composition to Predicate Device #1; the only difference being an expansion to the Intended Use / Indications For Use.

The catheter functions by being inserted by a trained physician into a patient by way of an introducer needle (17 Ga. needles recommended to be used to place 19 Ga. catheters, 18 Ga. needles recommended to be used to place 20 Ga. catheters). After placement to the desired peripheral nerve group, the introducer needle is withdrawn, leaving the catheter in place. An Epimed catheter connector (K051171), which is packaged with the device, can then be connected to the catheter which then allows for a standard Luer-lock connection point for a bacterial filter and/ or extension set and/or syringe/pump. Upon successful connection to the desired accessories, anesthetic agents may be delivered continuously or by bolus injection to the intended peripheral nerve group.

As the device is simple in design, there are few scientific concepts that apply; the catheter simply provides a conduit to deliver anesthesia. The polymer coated stainless steel spring has been proven to resist kinking, collapsing and shearing, and has the ability to withstand a minimum acceptable tensile force. The materials used to construct the device have been tested for compatibility with drugs used for performing peripheral nerve blocks. The catheter injection ports have been designed to remain patent and deliver injectants at a flow rate sufficient for the intended use. Lastly, the catheter and the connector with which it is packaged have been tested and proven to be compatible with each other.

There are no technological differences among the subject and predicate devices as the subject device, as well as both predicates, are:

- Single-use, disposable devices consisting of a polymer coated stainless steel spring.
- Available in various lengths, as well as open-ended or closed-ended configurations; the closed-ended models having three eyes (injection ports) at the distal end.
- Available in styletted or non-styletted versions.
- Available in 19 Ga. or 20 Ga. models.

Each catheter functions by being inserted by a trained physician into a patient by way of an introducer needle. After placement to the desired location, the introducer needle is withdrawn, leaving the catheter in place. A catheter connector can then be connected to the catheter which then allows for a standard Luer-lock connection point for a bacterial filter and/ or extension set and/or syringe/pump. Upon successful connection to the desired accessories, anesthetic agents may be delivered continuously or by bolus injection to the intended peripheral nerve group.

As the technologic characteristics across all of the referenced devices are identical, there is no effect on substantial equivalence.

Nonclinical Testing:

The results of the performance testing performed, i.e. dimensional, substance compatibility, kink testing, stiffness, tensile strength, connector attachment, flow test, resistance to leakage during aspiration or vacuum, resistance to leakage under pressure, corrosion resistance and skive testing, demonstrate that the Spirol® Block Continuous Peripheral Nerve Block Catheter performs comparably to, and is substantially equivalent to Predicate Device #1 (K981329) and Predicate Device #2 (K122027).

Pre-Clinical Design Validation studies have been performed on the Spirol® Block Continuous Peripheral Nerve Block Catheter. Based on the evaluation results, the Spirol® Block has been proven to conform to physician's needs, is suitable for its intended use, meeting the requirements of the Design Inputs.

In accordance with the applicable sections of ISO 10993, the relevant patient contacting components have been shown to meet the necessary biocompatibility requirements. The biocompatibility of the materials used to manufacture the Spirol® Block have been proven substantially equivalent through laboratory testing performed and documented in the Spirol® Catheter Biocompatibility Assessment. The biocompatibility testing which has been performed includes the following:

- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)
- Irritation or Intracutaneous Reactivity (per ISO 10993-10)
- Acute Systemic Toxicity (per ISO 10993-11) *catheter only*
- Sub-acute / Sub-chronic Toxicity (per ISO 10993-11) *catheter only*
- Genotoxicity (per ISO 10993-3) *catheter only*
- Implantation (per ISO 10993-6) *catheter only*

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Lastly, in accordance with ISO 10993-18 Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials) Annex C (Principles for Judging Toxicological Equivalency) part c) The materials comprising the Spirol® Block have already been established in a more invasive comparable exposure (Epidural applications) than this less invasive proposed application (Peripheral applications).

Conclusions:

The results of bench and laboratory testing demonstrate that Epimed's Spirol® Block Continuous Peripheral Nerve Block Catheter is substantially equivalent to the cited predicate devices.

Preston H. Frasier
Manager – QA/RA
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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

May 28, 2014

Epimed International, Inc.
Preston Frasier
Manager – QA/RA
141 Sal Landrio Dr.
Crossroads Business Park
Johnstown, NY 12095

Re: K133316
Trade/Device Name: Spirol Block Continuous Peripheral Nerve Block Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: April 21, 2014
Received: April 28, 2014

Dear Mr. Frasier:

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.

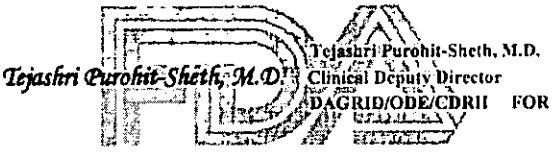
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
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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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133316

Device Name
The Spirol® Block Continuous Peripheral Nerve Block Catheter

Indications for Use *(Describe)*
The Spirol® Block Continuous Peripheral Nerve Block Catheter permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques including upper extremity, lower extremity, abdominal and paravertebral locations for periods not exceeding 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)

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)*

Todd D. Courtney -S
2014.05.28 12:45:48 -04'00'

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