April 27, 2020

Epimed International Inc.
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200624
Trade/Device Name: Percutaneous Introducer
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia conduction catheter
Regulatory Class: Class II
Product Code: BSO
Dated: March 9, 2020
Received: March 10, 2020

Dear Mark Job:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K200624

Device Name
Percutaneous Introducer

Indications for Use *(Describe)*
The Percutaneous Introducer is intended to allow for the percutaneous placement of devices, such as catheters, needles or probes, in close proximity to nerves and around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle/introducer.

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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510(k) Summary

Submitter Information:

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Date Prepared: August 11, 2019

Device Name & Classification:

Device Trade Name: Percutaneous Introducer

Common Name: Catheter Introducer

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

Classification: Class II

Predicate Device Information: Predicate device ambit Introducer (K102460)

Reference Device Information: Flexible Introducer Cannula (K051860)

Device Description:

The Percutaneous Introducer is a single-use, disposable device consisting of a flexible polymer sheath with a molded plastic hub. The device incorporates a stainless steel needle inside the flexible cannula and is removed after the introducer is placed. The inserted stainless steel introducer needle has a sharp distal point.

The flexible cannula acts as a conduit for percutaneous introduction of medical devices, such as catheters, needles, or probes. A stylet or porous plug (to prevent aspiration during insertion) comes seated in the standard 6 degree luer fitting of the proximal end of the needle hub. The Percutaneous Introducers are used for a short period of time and are supplied sterile and non-pyrogenic.

The Percutaneous Introducer is available in four lengths and a 14 gauge.

Statement of Intended Use:

The Percutaneous Introducer is intended to allow for the percutaneous placement of devices, such as catheters, needles, or probes, in close proximity to nerves and around or into surgical wound or non-surgical wound sites. It may be used to inject or aspirate the introduction area via the luer hub of the needle/introducer.

The intended use statement for the Percutaneous Introducer differs slightly from the intended use statement for the predicate device. In addition to some grammatical differences, the indications statement for the predicate device allows for "the percutaneous placement of catheters", while the Percutaneous Introducer allows for "the percutaneous placement of devices, such as catheters, needles, or probes". The most basic purpose of an introducer is to create a conduit from the outside of the patient's body to an area inside the patient's body. This conduit serves to allow other medical devices to be passed through in order to perform a procedure in the accessed location. The type of device that is passed through the conduit during the procedure does not affect the safety and effectiveness of the introducer itself.

The statement of intended use for the predicate device contains an additional sentence that specifies the intended user. This information is outlined in the Instructions for Use (IFU) for the Percutaneous Introducer and is not necessary in the intended use statement itself.

Intended Population:

The Percutaneous Introducer is intended for use with patients experiencing peripheral nerve pain.

Technological Characteristics and Substantial Equivalence:

Epimed's Percutaneous Introducer has identical Intended Use and Indications for Use as that of the predicate device, ambit Introducer (K102460). The Percutaneous Introducer itself is nearly identical in design, manufacture and material composition to reference device, Epimed's Flexible Introducer Cannula (K051860)

The Percutaneous Introducer functions by being inserted by a trained physician into a patient. It acts as a conduit for other medical devices, such as catheters, needles, or

probes. After placement to the desired location, the introducer needle is withdrawn. The device would be used only by trained/ licensed physicians in a clinical setting.

There are very few technological differences among the subject and predicate devices. The subject device, the predicate, and the reference device are sterile, single-use disposable devices. Technological differences between the subject and predicate devices include the polymer of the flexible cannula, the interface between stainless steel needle the flexible cannula, the cannula style, available lengths, and gauge size. These technological differences are all addressed by the reference device. The devices are intended to be used with other medical devices and do not contain software.

The devices are not intended to be implanted, but do come into contact with the patient as they are surgically invasive devices. Since the Percutaneous Introducer have limited contact duration with patients, the materials used to construct the device have been tested for ISO 10993 compliant biocompatibility, per FDA guidance. Furthermore, the device has been tested to verify resistance to collapsing and accordion/ peelback during tissue penetration. The device has also proven to possess the ability to withstand a minimum acceptable tensile force.

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

Nonclinical Testing:

The results of the performance testing performed, i.e. Penetrations Force Test, Simulated Use Penetration/ Withdrawal/ Accordion/ Peelback Test and Tensile Strength demonstrate that the Epimed's Percutaneous Introducer performs comparably to, and is substantially equivalent to predicate device (K102460).

Pre-clinical design validation studies have been performed on Epimed's Percutaneous Introducer. Based on the evaluation results, the Percutaneous Introducer has been shown 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, according to FDA guidance, the relevant patient contacting components have been shown to meet the

necessary biocompatibility requirements. The biocompatibility of the materials used to manufacture Percutaneous Introducer supports Substantial Equivalence to the predicate device through laboratory testing performed and documented in the Percutaneous Introducer Biocompatibility Assessment.

Testing per ISO 594-1, ISO 594-2, and ISO 10555-5 have been conducted, with successful results. Other tests performed include:

- Packaging- Sterility
- Burst Testing (ASTM F 1140)
- Dye Penetration (ASTM F 1929)
- Cytotoxicity (ISO10993-5:2009)
- Sensitization (ISO10993-10:2010)
- Irritation/ Intracutaneous Reactivity (ISO10993-10:2010)
- EtO Residuals (I-CHM-2136 Rev. 0)
- Pyrogenicity (ISO10993-12:2017)
- Rabbit Blood Hemolysis (ISO10993-12:2017)

Conclusion:

Epimed's Percutaneous Introducer and the predicate, ambit Introducer (K1022460) have the same indications for use. The introducer itself is nearly identical in design, manufacture and composition to reference predicate, Epimed's Flexible Introducer Cannula (K051860). The results of bench and laboratory testing demonstrate that Epimed's Percutaneous Introducer is substantially equivalent to the cited predicate devices.

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