March 8, 2019

Epimed International, Inc.
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K190256
Trade/Device Name: Rulo Radiofrequency Lesion Probe
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: Class II
Product Code: GXI
Dated: February 5, 2019
Received: February 7, 2019

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/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,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K190256

Device Name
Rulo™ Radiofrequency Lesion Probe

Indications for Use *(Describe)*
The Rulo™ Radiofrequency Lesion Probe is an injection probe which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

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: K190256

Submitter Information:

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Date Prepared:	January 23, 2019

Device Name & Classification:

Device Trade Name:	Rulo™ Radiofrequency Lesion Probe
Common Name:	Radiofrequency Lesion Probe
Classification Names:	Radiofrequency Lesion Probe, GXI (21 CFR 882.4725)
Models/Sizes:	300-1615 (16 gauge); 300-1815 (18 gauge)

Predicate Device(s) Information:

Predicate Device:	Diros OWL Sterile Single Use R.F. Insulated Cannulae Models 466 and DHC (K141586)

Device Description:

The Rulo™ Radiofrequency Lesion Probe (Rulo Probe) creates radiofrequency (RF) lesions on nerves and can also create percutaneous nerve blocks by delivering anesthetic to the site. It is a single-use, surgically invasive device. It is

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inserted with the use of a flexible introducer accessory to contact a nerve in an area of the spine for less than 15 minutes to treat pain. The RF energy creates a lesion on nerve tissue that conducts pain signals. The tissue's ability to conduct electrical signals is disrupted by the lesion. The targeted nerve can be localized either by using RF electrostimulation through the cannula or by injecting contrast medium through the cannula with the use of the fluid injection port and using radiography concomitantly. The nerve may be blocked by injecting local anesthetic solution or making an RF lesion. The device is used by a trained physician in a clinical setting.

The device is constructed with a steel cannula and uses a variety of polymers for the insulation, hub, cable, connector, cap and fluid injection port

The flexible introducer accessory was cleared in K051860. The fluid injection port was cleared as an extension set in K020926.

Statement of Intended Use:

The Rulo™ Radiofrequency Lesion Probe is an injection probe which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

The Rulo Radiofrequency Lesion Probe Intended Use/Indications for Use statement is essentially identical to that of the predicate device, Diros OWL Sterile Single Use R.F. Insulated Cannulae Models 466 and DHC (K141586).

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Technological Characteristics and Substantial Equivalence:

The Rulo Probe is similar in design and material composition to the predicate device, Diros OWL Sterile Single Use R.F. Insulated Cannulae Models 466 and DHC (K141586). Both have an insulated steel needle (cannula) where the opening in the insulation at the tip of the device delivers radiofrequency energy and fluid to the tissue it contacts. Both devices connect to radiofrequency generators and have a fluid port. The uninsulated delivery site on the cannula of the Rulo Probe is directional and can focus the energy and fluid to the desired tissue target while the Diros predicate device does not have the directional feature. The Diros device has a sharp tip for direct insertion into the tissue while the Rulo Probe is inserted with a flexible introducer accessory.

Nonclinical Testing:

The results of the performance testing, demonstrate that the Epimed Rulo™ Radiofrequency Lesion Probe performs comparably to and is substantially equivalent to the predicate device (K141586).

There is not a harmonized standard or guidance document that directly applies to radiofrequency lesion devices. Applicable tests and requirements have been adopted from the following standards to compile the suite of performance testing:

ISO **594-1** Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements

ISO **594-2** Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: Lock Fittings

BS **6196** British Standard Specification for Sterile Epidural Catheters and Introducer Needles for Single Use

ANSI/AAMI/ EN **60601-1** Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

ISO **7864** Sterile Hypodermic Needles for Single Use

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In accordance with the applicable sections recommended per ISO **10993-1**, the relevant patient contacting components have been shown to meet the necessary biocompatibility requirements. The biocompatibility of the materials used to manufacture the Rulo Probe have been tested and analyzed with discussion in the 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**)
- Systemic Toxicity (per ISO **10993-11**)

The flexible introducer accessory is made of stainless steel and was cleared in K051860. The fluid port is made of PVC and was cleared as an extension set in K020926.

Conclusions:

Epimed's Rulo Radiofrequency Lesion Probe and the predicate device, Diros OWL Sterile Single Use R.F. Insulated Cannulae Models 466 and DHC (K141586), have the same intended use/indications for use and the probes are very similar in technological characteristics, including the overall design, dimensions, delivery of RF energy and fluids, and choice of materials.

There are some minor differences in technological characteristics that do not raise new questions of safety or efficacy. The predicate device has an active tip that does not direct the energy or fluids in a specific direction. The Rulo Probe has a focused active tip for directionality in delivery of RF energy, and this direction is indicated by the handle. The predicate device has a sharper tip and can be inserted directly into the tissues, the while Rulo Probe has a blunt tip, and is inserted into the tissue with the use of a flexible introducer accessory. This accessory has been cleared in in the marketplace for several years, and does not present any new questions of safety or efficacy.

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In additional to the same intended use, the technological characteristics are the same or similar, and where there are minor differences, there are not new or different questions of safety or efficacy, as demonstrated by bench and laboratory testing. Epimed's Rulo Radiofrequency Lesion Probe is substantially equivalent to the predicate device.

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