IMEDICOM Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt,
Irvine, California 92620

Re: K173541
Trade/Device Name: EPINAUT
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: July 12, 2018
Received: July 19, 2018

Dear Priscilla Chung:

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)*

K173541

Device Name
EPINAUT

Indications for Use *(Describe)*
For administration of anesthetic agents into the epidural space to provide epidural or caudal anesthesia.

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

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 12, 2018

1. Applicant / Submitter

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2. Submission Correspondent

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3. Device

- Trade Name: EPINAUT
- Common Name: Anesthesia conduction catheter
- Classification Name: Anesthesia conduction catheter
- Product Code: BSO
- Classification regulation: Class II, 21 CFR 868.5120

4. Predicate Device:

- Racz Epidural Catheter by Epimed International, Inc. (K954584)

5. Description:

EPINAUT Spring Guide Epidural Catheter is constructed of a stainless steel continuous spring. EPINUAT Spring Guide Epidural Catheter offers two types of catheter. The catheter types, L330 & L600 have an uncoated distal tip which is flexible, smooth and

rounded with coils slightly spread for maximum flexibility and lateral distribution of injectant. The other catheter types, C310 & C600 have a distal end which is entirely coated by tube for maximum smoothness. There are 16 models in EPINAUT: L33011320, L33013820, L33011315, L33013815, L60011320, L60013820, L60011315, L60013815, C31011320, C31013820, C31011315, C31013815, C60011320, C60013820, C60011315 and C60013815. Each model is characterized by different length of catheter, length and outer diameter of wire, inner diameter of adapter, length and diameter of introducer needle and needle cap.
EPINUAT Spring Guided Epidural Catheter have enhanced tensile/ break strength and restrict longitudinal catheter stretch, while the spring coils make the catheter resistant to kinking and collapsing. Wire is also provided with the device which consists of a stainless steel and a molded plastic hub.
The introducer needle is inserted into the epidural space through the sacral hiatus under intermittent fluoroscopy. After appropriate determination of the epidurogram and target area, the catheter with the wire in it is advanced through the introducer needle to the concerned area as determined by MRI or symptomatology. When the catheter is approached to target site, the wire is removed from the catheter and then the medication can be injected by attaching the adapter to a syringe.
The intended population of the device is the patient with chronic low back pain and contained disc herniations.

6. Indication for use:

For administration of anesthetic agents into the epidural space to provide epidural or caudal anesthesia.

7. Basis for Substantial Equivalence

EPINAUT is substantially equivalent to the Racz Epidural Catheter (K954584) made by Epimed International, Inc.
There are no significant differences between the subject devices and the predicate device. The subject devices have the same intended use as the identified predicate device and they are similar in fundamental scientific technology, design, and size, and they are sterilized via Ethylene Oxide gas.
The materials used in the subject devices might be different from the predicate device; however, the biocompatibility testing results of the subject device support that the subject devices are biocompatible and the performance testing results show that the subject device would perform as well as the predicate device.

	Subject Device	**Predicate Device**
Device Name	**EPINAUT**	**Racz Epidural Catheter**
510(k) Number	-	K954584

Product Code		BSO	BSO
Manufacturer		IMEDICOM Co., Ltd.	Epimed International, Inc.
Indications for Use		For administration of anesthetic agents into the epidural space to provide epidural or caudal anesthesia.	For administration of anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia.
Device	**Diameter(O.D.) of Catheter**	19~20G	19~21G
	Length of Catheter	31~60cm	30~84.5cm
	Material	Stainless Steel, Teflon, ABS	Stainless Steel, FEP, ABS
	Tip type	Coil Spring Type	Coil Spring Type
	Single use	Yes	Yes
	Components	Catheter, Adapter, Introducer Needle	Catheter, Adapter, Introducer Needle
	Biocompatibility	Biocompatible	Biocompatible
Endoscope capable		Incapable	Incapable
Sterilization		Ethylene Oxide Gas Sterilization	Ethylene Oxide Gas Sterilization

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11135 and ISO 11737-1, 2 to verify the sterility assurance level (10^{-6}).
- The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 3 year shelf life.
- The epidural catheter, wire, adapter, introducer needle, and needle cap are the patient contacting components and they are categorized as External communicating device (tissue/bone/dentin communicating), Limited exposure (<24 hours). Biocompatibility tests were performed in accordance with ISO 10993-4, 5, 10, 11 and USP 39 <151>, and the test results supported that the subject devices are biocompatible.
- Various bench tests were performed to evaluate the performance of the subject devices and the test results met the pre-set criteria. Below is the list of the tests performed.

No.	Test
1	Visual Inspection (Appearance)
2	Size Measurement
3	Leakage Test (Catheter)
4	Tensile strength (Catheter)

5	Assemble compatibility (Catheter)
6	Radiopacity test
7	Corrosion resistance test
8	Flexural Rigidity (Catheter introducer and the needle)
9	Pulling (Drawing) Test (Catheter introducer and the needle)
10	Flexural Rigidity (Wire)
11	EO Gas residue
12	Sterility Test
13	Endotoxin Test
14	Particulate Matter Test

We also performed side by side testing to compare performance of the subject device and the predicate device as below.

No	Test Item		Standard
1	Tensile strength	Catheter	ISO 10555-1 Annex B
		Catheter-Hub	BS 6196:1989 Appendix D
		Stylet	BS 6196:1989 Appendix D
		Needle Stylet	BS 6196:1989 Appendix F
2	Dullness test		BS 6196:1989 Appendix G
3	Fluid pressure of the catheter/ adapter connection		ISO 10555-1 Annex G
4	Flow rate		ISO 10555-1 Annex E
5	Luminal integrity		ISO 10555-1 Annex C

The test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

Based on the similarities, we conclude that the EPINAUT is substantially equivalent to the predicate devices.