May 3, 2019

Relievant Medsystems
Ms. Laurie Hook
Clinical/Regulatory Consultant
358 Moffett Park Drive, Suite 105
Sunnyvale, California 94089

Re: K190504
Trade/Device Name: Intracept Intraosseous Nerve Ablation System (RF Probe), Intracept Intraosseous Nerve Ablation System (Access Instruments), Relievant RF Generator
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI

Dated: February 28, 2019
Received: March 1, 2019

Dear Ms. Hook:

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,

for Carlos L. Peña, PhD, MS
Director
Office of Neurological and Physical Medicine 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)*
K190504

Device Name
Intracept Intraosseous Nerve Ablation System
Relievant Medsystems RF Generator (RFG)

Indications for Use *(Describe)*
The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant Intracept Intraosseous Nerve Ablation System for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

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.

510(k) SUMMARY -K190504

Applicant's Name and Address:
Relievant Medsystems, Inc.
1230 Midas Way, Suite 200
Sunnyvale, CA 94085-4068

Contact Person: Laurie Hook
Telephone: 650/368-1000
Facsimile: 650/298-9205

Date Prepared: April 29, 2019

Device Name:

Device Generic Name: RF Ablation Catheter and Accessories;
RF Generator

Device Trade Name: Intracept Intraosseous Nerve Ablation System;
Relievant Medsystems RF Generator (Relievant RFG)

Device Classification: II

Classification Name: Radiofrequency lesion probe, 21 CFR 882.4725, Product Code GXI
Radiofrequency lesion generator, 21 CFR 882.4400, Product Code GXD

Predicate Device:

Relievant Medsystems, Inc.: Intracept Intraosseous Nerve Ablation System (K180369, K170827) and Relievant RFG (K171143)

Device Description:

The Intracept Intraosseous Nerve Ablation System (Intracept System) is comprised of sterile, single-use components:

- The Intracept Access Instruments include introducers, cannulas and stylets that provide access to the intended site of radiofrequency (RF) ablation.
- The Intracept RF Probe conducts RF energy to the target location.

To obtain the energy needed for tissue ablation, the Intracept RF Probe is used with the Relievant RFG.

The Intracept System technique uses RF ablation of the basivertebral nerve for relief of chronic low back pain and involves a two-step process. First, utilizing the Access Instruments, based on a minimally invasive, transpedicular or extrapedicular approach, a cannula and stylets are placed into the vertebral body to create a path or channel to the terminus of the basivertebral foramen. The RF Probe is then placed into this channel at the terminus of the basivertebral foramen and controlled RF energy is delivered to ablate the basivertebral nerve. This nerve has been identified as a proprioceptive sensory nerve with enervation of the vertebral endplates.

Indications for Use

The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant Intracept Intraosseous Nerve Ablation System for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

Substantial Equivalence

Compared to the Predicate Devices (Intracept System and Relievant RFG), there have been no design changes to the Intracept System or the Relievant RFG. The only difference between the Subject and Predicate Devices is the Indications for Use Statement. The Indications for Use Statements for the Subject Devices have been modified based on historical and current use of the Modic classification to include characteristics of each Modic Type following the references to Modic Type 1 and Type 2 based on MRI. The modification does not describe a new disease condition or patient population that the Subject Devices are intended to treat. The modification is intended to aid clinicians in their interpretation of MRI findings.

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device Component	**Subject:** Intracept System: RF Probe Access Instruments RF Generator	**Predicate:** Intracept System: RF Probe (K180369) Access Instruments (K170827) RF Generator (K171143)	--
Intended Use	To ablate the basivertebral nerves of the L3 to S1 vertebrae		Equivalent
Intracept System Indication	The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).	The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with RF generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI.	Equivalent Different

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Relievant RFG Indication	The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant Intracept Intraosseous Nerve Ablation System for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).	The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant Intracept Intraosseous Nerve Ablation System for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI.	Equivalent Different
Principle	Provide bipolar RF energy to the tissue between and around the electrodes to achieve tissue ablation (i.e., cellular necrosis through thermal ablation)		Equivalent
Treatment Parameters: Temperature Ramp Time	 85° C 1°C/second 15 minutes (900 seconds)		 Equivalent Equivalent Equivalent
Access Instruments and RF Probe: Design Materials Use	 No changes No changes Single		 Equivalent Equivalent Equivalent
Connect to RF Generator	Cable integrated with RF Probe		Equivalent
RF Generator: Operating Mode Output: Power Frequency Feedback mechanism	 Bipolar energy 20W 475 KHz Temperature controlled		 Equivalent Equivalent Equivalent Equivalent

Non-Clinical Performance Testing

No design changes were made to the Subject Devices. Substantial equivalence is not dependent upon non-clinical clinical performance testing.

Clinical Performance Testing

Substantial equivalence is not dependent upon clinical data and no clinical testing was performed.

Conclusions

The Indications for Use Statements of the Subject Devices have been modified to include characteristics of each Modic Type following references to Modic Type 1 and Type 2 based on MRI. The modification does not raise different questions of safety or effectiveness. There were no design changes to the Subject Devices. These results support the substantial equivalence of the Subject and Predicate Devices.