March 11, 2022

Relievant Medsystems, Inc.
Thomas Slater
VP, Quality and Regulatory Affairs
1230 Midas Way, Suite 200
Sunnyvale, California 94085

Re: K213836
Trade/Device Name: Intracept Intraosseous Nerve Ablation System
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: January 6, 2022
Received: January 23, 2022

Dear Thomas Slater:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213836

Device Name
Intracept Intraosseous Nerve Ablation System

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).

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.

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5. 510(k) SUMMARY

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

Contact Person: Thomas A. Slater
Telephone: 650/368-1000 x135
Facsimile: 650/298-9205

Date Prepared: January 6, 2022

Device Name:

Device Generic Name: RF Ablation Catheter and Accessories

Device Trade Name: Intracept Intraosseous Nerve Ablation System

Device Classification: II

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

Predicate Device:

Relievant Medsystems, Inc.: Intracept Intraosseous Nerve Ablation System (K190504)

Reference Devices:

Relievant Medsystems, Inc.: Intracept Intraosseous Nerve Ablation System:

- Intracept RF Probe (K180369)
- Access Instruments (K170827)

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 Radiofrequency Generator (RFG).

The Intracept System 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 (BVN). 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).

Substantial Equivalence

Compared to the Predicate Device, there have been no changes to the patient population or the Indications for Use for the Intracept System. The Subject and Predicate Devices have a functionally equivalent design, with the difference being the introduction of an additional set of ablation parameters for ablation of the basivertebral nerve. The data provided herein demonstrates substantial equivalence to the Predicate Device.

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device Component	**Subject:** Intracept System	**Predicate:** Intracept System (K190504) **Reference Devices:** RF Probe (K180369) Access Instruments (K170827)	--
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).		Equivalent
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
Ablation Parameters: Temperature Ramp Time	85° C 1°C/second 15 minutes (900 seconds)	85° C 1°C/second 15 minutes (900 seconds)	Equivalent Equivalent Equivalent
	75° C 0.5°C/second 7 minutes (420 seconds)	--	Different
Access Instruments: Design	No changes		Equivalent
Materials	No changes		Equivalent
Use	Single		Equivalent
RF Probe: Design	Removal of SensTx Chip	Optional SensTx Functionality	Different
Materials	No changes	No changes	Equivalent
Use	Single	Single	Equivalent

Non-Clinical Performance Testing

Risk analysis of an additional set of ablation parameters at lower temperature, ramp, and time showed no increase in risk profile.

Conclusions

Based upon non-clinical performance testing, the Subject Device (Intracept System) with additional ablation parameters performs as intended and does not raise any new safety and/or efficacy concerns when compared to the legally marketed Predicate Device (Intracept System); therefore, these results support the substantial equivalence of the Subject and Predicate Device.