September 14, 2018

Relievant Medsystems
Alex DiNello
Chief Operating Officer
385 Moffett Park Drive, Suite 105
Sunnyvale, California 94089

Re: K180369
Trade/Device Name: Intracept Intraosseous Nerve Ablation System (component Intracept RF Probe)
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: Class II
Product Code: GXI
Dated: August 13, 2018
Received: August 15, 2018

Dear Alex DiNello:

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)*
K180369

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 either Type 1 or Type 2 Modic changes on an MRI.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Applicant's Name and Address:
Relievant Medsystems, Inc.
385 Moffett Park Drive, Suite 105
Sunnyvale, CA 94089-1218

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

Date Prepared: August 13, 2018

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 (K153272)

Device Description:

The Intracept Intraosseous Nerve Ablation System (Intracept System) is comprised of two 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 RF Generator (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 either Type 1 or Type 2 Modic changes on an MRI.

Substantial Equivalence

The subject device (Intracept RF Probe -- a component of the Intracept System) has the same intended use, has a similar overall design, and has the same operational characteristics as the predicate device (Flexible Bi-Polar RF Probe). Differences between the RF Probe devices do not raise different questions of safety and effectiveness for the subject device. In this submission, no modifications were made to the Intracept System's Access Instruments.

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device Component	**Subject:** Intracept RF Probe	**Predicate:** Intracept Flexible Bi-Polar RF Probe (K153272)	--
Intended Use	To ablate the basivertebral nerves of the L3 to S1 vertebrae		Same
Indication	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.		Same
Principle	Provide bipolar RF energy to the tissue between and around the electrodes to achieve tissue ablation (i.e., cellular necrosis through thermal ablation)		Same
Probe Shaft Length/Diameter	335mm/1.98mm	335mm/1.98mm	Same
Distal Tip Length	4mm	4mm	Same
Electrodes	Two	Two	Same
Safety cable	Tether welded to distal electrode ensures the electrode tip is retained for device removal	--	Different
Tip temperature monitor/control	Thermocouple at distal tip	Thermocouple at distal tip	Same
SensTx Chip	Treatment parameters stored on microchip in RF Probe Handle	--	Different
Treatment Parameters Temperature Ramp Time	 85° C 1°C/second 15 minutes (900 seconds)	 85° C 1°C/second 15 minutes (900 seconds)	 Same Same Same
Indicators	Circumferential markings (exit of Curved Cannula and clearance for electrode) Light Ring	Circumferential markings (exit of Curved Cannula and clearance for electrode) --	Same Different
Materials: Patient Contact	Stainless steel and Polyether Block Amide	Stainless steel and Polyether Block Amide	Same
Connect to RFG	Cable integrated with RF Probe	Separate cable	Different
Sterilization	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
Use	Single	Single	Same

Non-Clinical Performance Testing

Testing of the Intracept RF Probe demonstrated that the device met specifications and performance requirements, and supports demonstration of equivalence to the predicate device. Performance testing of the subject device was completed as follows:

Test	Test Method Summary	Results
Biocompatibility Testing Patient contact materials are classified as tissue/bone/dentin <24 hours and tested for compliance to applicable ISO 10993 standards. The subject device is the same classification as the predicate and the materials used in construction are equivalent.		
RF Probe Tip: ≤ 24 hour contact with Tissue/Bone/Dentin		
Cytotoxicity	ISO 10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (MEM Elusion)	PASS
Sensitization	ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Sensitization)	PASS
Acute Systemic Toxicity	ISO 10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity (Acute Systemic Injection Test in Mice)	PASS
Intracutaneous Reactivity	ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Intracutaneous Reactivity Irritation Test in Rabbits)	PASS
RF Probe Handle: ≤ 24 hour contact with Intact Skin		
Cytotoxicity	ISO 10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (MEM Elusion)	PASS
Sensitization	ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Sensitization)	PASS
Intracutaneous Reactivity	ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Intracutaneous Reactivity Irritation Test in Rabbits)	PASS
Functional Testing The subject and predicate devices are equivalent in size, materials and construction.		
Corrosion	Corrosion testing per ISO 10555-1 Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (Annex A: No visible signs of corrosion)	PASS
Transit	ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems (DC 13, assurance level II)	PASS
Gross Leaks	ASTM F 2096 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	PASS
Seal Strength	ASTM F88/F88M - Standard Test Method for Seal Strength of Flexible Barrier Materials (Seal peel ≥1.0 lbs/in)	PASS
Sterilization	ISO-11135 – Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices (Sterility assurance of 10^{-6})	PASS
Electrical Safety Testing The subject and predicate devices are used with the same Relievant RF Generator and were evaluated for		

Test	Test Method Summary	Results
compliance with the electrical safety standard; results demonstrated equivalence.		
Electrical	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance and IEC 60601-2-2 Medical electrical equipment-Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	PASS
Electromagnetic Compatibility (EMC)	IEC 60601-1-2 Medical electric equipment-Part 1-2: General requirements of safety-Collateral Standard: Electromagnetic compatibility-Requirements and Tests	PASS
Interface and Primary Operating Function Testing The subject and predicate devices have equivalent performance.		
SensTx® Chip	Assessed use with Relievant RFG software recognition and integration of SensTx Chip	PASS
Programmable Electrical Medical Systems (PEMS)	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	PASS
Simulated Use with Mechanical Testing	Met performance specifications for mechanical durability and simulated use, as well as compatibility with Access Instruments.	PASS
Usability	IEC 62366-1: Application of Usability Engineering to Medical Devices and IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for basic safety and essential performance – Collateral Standard: Usability	PASS

No modifications were made to the Intracept Access Instruments; therefore, previous testing remains applicable.

Clinical Performance Testing

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

Conclusions

Based upon device comparison and non-clinical performance testing, the Intracept System with the RF Probe and Access Instruments is substantially equivalent to the legally marketed predicate device (Intracept System with the Flexible Bi-Polar RF Probe and Access Instruments) and any differences in design or technologic characteristics do not raise different questions of safety or effectiveness. All test requirements were met and results support the substantial equivalence of the subject and predicate devices.