October 26, 2022

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

Re: K222281
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: July 28, 2022
Received: July 29, 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)*
K222281

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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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
Cell Phone: 408/835-8139
Facsimile: 650/298-9205

Date Prepared: October 26, 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 (K213836)

Reference Devices:

Relievant Medsystems, Inc.: Intracept Intraosseous Nerve Ablation System:
- Intracept RF Probe (K180369)
- Intracept Access Instruments (K170827)

Relievant Medsystems, Inc.: Relievant Radiofrequency Generator (K171143)

Device Description:

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

- The Intracept Access Instruments include 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 Relievant RFG is a universal AC powered, microcontroller controlled, bipolar RF generator intended to deliver RF energy to a targeted site. During RF energy delivery, power is continuously monitored and controlled, based on temperature and impedance measurements at the treatment site, to ensure proper operation. Currently, the Relievant RF Generator (reference device (K171143)) is the only compatible RF generator for use with the Intracept System.

The Intracept System uses RF energy to ablate 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 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).

Substantial Equivalence

The Subject Device (Intracept Access Instruments, a component of the Intracept System) has the same intended use, patient population, Indications for Use, principles of operation, and sterilization method as the Predicate Device (Intracept System). Changes were made to facilitate usability and performance. Based on the device comparison and non-clinical performance testing, the modifications do not raise any new questions of safety or effectiveness and support the substantial equivalence of the Subject and Predicate Devices. No modifications were made to the Intracept System's RF Probe.

Characteristic	**Relievant Medsystems**	**Relievant Medsystems**	**Comparison**
Device	**Subject: Intracept System**	**Predicate: Intracept System**	
510(k)	--	(K213836)	
FDA Classification/ Product Code	II GXI	II GXI	Same
Intended Use	To ablate the basivertebral nerves of the L3 to S1 vertebrae.		Same
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).		Same
Target Population	Chronic low back pain		Same
Anatomical Site	Basivertebral nerves L3-S1 vertebrae		Same
Where Used	Surgical setting		Same

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device	**Subject: Intracept System**	**Predicate: Intracept System**	
Device Component	**Intracept Access Instruments**	**Intracept Access Instruments Reference Device (K170827)**	--
TECHNICAL			
Principle	Minimally invasive percutaneous transpedicular or extrapedicular access through the vertebral body to allow passage of the RF Probe.		Same
Components	Introducer Stylets: • Diamond Stylet • Bevel Stylet Cannulas: • Introducer Cannula • Curved Cannula Stylets: • J-Stylet • Straight Stylet Drill	Introducer Stylets: • Trocar Stylet • Bevel Stylet Cannulas: • Introducer Cannula • Curved Cannula Stylets: • J-Stylet • Straight Stylet	Equivalent (performance & usability improvements) Equivalent (performance & usability improvements) Equivalent (performance & usability improvements) **Additional Subcomponent**
Materials: Tissue/Bone Contact	• 304 stainless steel • PEEK • Nitinol • Silicone fluid • 17-4PH stainless steel	• 304 stainless steel • PEEK • Nitinol • -- • --	Same Same Same **Different** **Different**
Materials: Handles - Intact Skin Contact	• Polycarbonate with colorant • Ink • -- • Glass-filled nylon with colorant, 303 / 304 stainless steel	• Polycarbonate with colorant • Ink • 316 / 17-7PH stainless steel, silicone fluid • --	**Different** **Different** **Different** **Different**
Materials: Non Contact (contained within handles)	• -- • 303 / 316 stainless steel	• 304 stainless steel, platinum/iridium • --	**Different** **Different**
Indicators/ Markings	• Numeric indicators on handles to signify procedural step • Directionality indicated with arrows • Reference depth markers • -- • Visible red indicator to notify that Bail tab is open	• Numeric indicators on handles to signify procedural step • Directionality indicated with arrows • Reference depth markers • Gap Indicator: Indicates when Wing Nut is making contact with the Introducer Cannula • --	Equivalent Equivalent Equivalent **Different** **Different**
Packaging	Double barrier thermoformed tray with a retainer lid and Tyvek over lids	Double barrier thermoformed tray with a retainer lid and Tyvek over lids	Same (packaging concept)
Sterilization	Gamma irradiation SAL 10^{-6}	Gamma irradiation SAL 10^{-6}	Same

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device	**Subject: Intracept System**	**Predicate: Intracept System**	
Shelf life	6-month: Pass 2-year: In-Process	6-month: Pass 2-year: Pass	Same **Different**
Device Component	**Intracept RF Probe**	**Intracept RF Probe Reference Device (K180369)**	**Same**

Non-Clinical Bench Testing

The Intracept System with modified Access Instruments met specifications and performance requirements and is equivalent to the Predicate Intracept System. Non-clinical bench testing included mechanical durability with simulated use and usability. Biocompatibility, packaging, sterilization and shelf-life validation testing of the Subject Device were performed and met all applicable requirements of the relevant standards.

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.		
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
Dimensional and 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 F2096 - 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
Mechanical	Met all performance testing per Product Specifications	PASS
Sterilization	ANSI/AAMI/ISO 11137-1: Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ANSI/AAMI/ISO 11137-2: Part 2: Establishing the sterilization dose (Sterility assurance of 10^{-6})	PASS
Interface and Primary Operating Function Testing The Subject and Predicate Devices have equivalent performance.		
Simulated Use	Following exposure to 6 full deployments, devices remained functional without damage and met interface requirements.	PASS
Usability	IEC 62366-1: Application of Usability Engineering to Medical Devices Usability testing simulated in sawbones with 15 users of the Intracept Intraosseous Nerve Ablation System (Access Instruments and RF Probe) were safe and effective for intended users, uses and use environments.	PASS

No modifications were made to the RF Probe, 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 non-clinical performance testing, the Subject Device (Intracept System with modified Access Instruments) performs as intended and does not raise any new questions of safety or effectiveness when compared to the legally marketed Predicate Device (Intracept System); therefore, these results support the substantial equivalence of the Subject and Predicate Device.