DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 9, 2017

Relievant Medsystems
Ms. Laurie Hook
Clinical/Regulatory
2688 Middlefield Road, Suite A
Redwood City, California 94063

Re: K170827
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 7, 2017
Received: July 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170827

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 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.

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.
2688 Middlefield Road, Suite A
Redwood City, CA 94063

Contact Person: Laurie Hook
Telephone: 650/368-1000
Facsimile: 650/298-9205
Date Prepared: July 7, 2017

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:

INTRACEPT® Intraosseous Nerve Ablation System (K153272)

Device Description:

The INTRACEPT® Intraosseous Nerve Ablation System is comprised of two sterile, single use components:

- The INTRACEPT Access Instruments include trocars, cannulas and stylets that provide access to the intended site of radiofrequency (RF) ablation. This submission describes modifications to the Access Instruments to improve ease of use compared to the predicate, Easy Access Instrument Set.

- The INTRACEPT Flexible Bi-Polar RF Probe conducts RF energy to the target location. There have been no changes to this component; therefore, there is no impact on RF ablation.

Additionally, a commercially available, legally marketed, RF Generator that has been confirmed by Relievant to be compatible, provides RF energy to the RF Probe. An Interconnect Cable connects the RF Probe to the RF Generator.

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 is placed into the vertebral body to create a path or channel to the terminus of the basivertebral foramen. An RF Probe is then placed into this channel at the terminus of the basivertebral foramen, and controlled RF energy is delivered to destroy 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

Compared to the previously cleared INTRACEPT Easy Access Instrument Set, the INTRACEPT Access Instruments have the same indication, the same intended use, the same overall design and the same operational characteristics. Modifications to the Access Instruments were made to improve their ease of use. No modifications were made to the INTRACEPT Flexible Bi-Polar RF Probe.

Characteristic	Relievant Medsystems	Relievant Medsystems	Comparison
Device Component	Subject: INTRACEPT Access Instruments	Predicate: INTRACEPT Easy Access Instrument Set (K153272)	--
Intended Use	To create a path or channel to the terminus of the basivertebral foramen.		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	Minimally invasive percutaneous transpedicular or extrapedicular access through the vertebral body to allow passage of the RF probe		Same
Instruments	Introducers: • Trocar Introducer • Bevel Introducer Cannulas: • Introducer Cannula • Curved Cannula Stylets: • J-Stylet • Straight Stylet	Introducers: • Trocar Introducer • -- Cannulas: • Introducer Cannula • Curved Cannula Stylets: • J-Stylet • Straight Stylet	Same and added Bevel Introducer as an additional tip style
Indicators	Added Gap Indicator to the Introducer Cannula; removed circumferential depth marker on the Straight Stylet	Visual estimation of depth performed by operator using depth marker	Different
Materials: Patient Contact	Stainless steel, PEEK, Nitinol	Stainless steel, PEEK with $BaSO_4$, Nitinol	Same and PEEK without $BaSO_4$
Sterilization	Gamma irradiation	Ethylene Oxide	Different
Device Component	Subject: INTRACEPT Flexible Bi-Polar RF Probe	Predicate: INTRACEPT Flexible Bi-Polar RF Probe (K153272)	Same

Non-Clinical Testing

The INTRACEPT Access Instruments met specifications and performance requirements, and are equivalent to the predicate INTRACEPT Easy Access Instrument Set. Performance testing of the INTRACEPT Access Instruments was provided in support of the substantial equivalence determination 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.		
Cytotoxicity	ISO 10993-5: 2009 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (MEM Elusion)	PASS (Equivalent materials, same testing as for predicate device.)
Sensitization	ISO 10993-10: 2010 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Sensitization)	PASS (Equivalent materials, same testing as for predicate device.)
Acute Systemic Toxicity	ISO 10993-11: 2006 – Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity (Acute Systemic Injection Test in Mice: Saline and Cottonseed Oil Extracts)	PASS (Equivalent materials, same testing as for predicate device.)
Intracutaneous Reactivity	ISO 10993-10: 2010 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Intracutaneous Reactivity Irritation Test in Rabbits: Saline and Cottonseed Oil Extracts)	PASS (Equivalent materials, same testing as for predicate device.)
Dimensional and Functional Testing The subject and predicate devices are equivalent in size, materials, and construction.		
Corrosion	Corrosion testing per ISO 10555-1:2013 - Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (Annex A: No visible signs of corrosion)	PASS
Transit	ASTM D4169-14 - Standard Practice for Performance Testing of Shipping Containers and Systems (DC 13, assurance level II)	PASS
Gross Leaks	ASTM F 2096-11 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	PASS
Seal Strength	ASTM F88/F88M-15 - Standard Test Method for Seal Strength of Flexible Barrier Materials (Seal peel >1.0 lbs)	PASS
Mechanical	Met all performance testing per Product Specifications: - Introducer Cannula: Tensile & Torque - Trocar/Bevel Introducer: Tensile & Torque	PASS

Test	Test Method Summary	Results
	- Curved Cannula: Tensile & Torque - J-Stylet: Tensile - Straight Stylet: Tensile	
Sterilization	ANSI/AAMI/ISO 11137-1: 2006 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		
Simulated Use	Following exposure to 6 full deployments, devices remained functional without damage and met interface requirements.	PASS
Usability	IEC 62366-1: 2015: Application of Usability Engineering to Medical Devices. Usability testing simulated in sawbones with 16 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 INTRACEPT Flexible Bi-Polar RF Probe; therefore, previous testing of the RF Probe (i.e., biocompatibility, electrical safety, dimensional and functional, temperature accuracy, and lesion) remains applicable for the INTRACEPT Intraosseous Nerve Ablation System (Flexible Bi-Polar RF Probe with the Access Instruments) and retesting was not needed.

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 bench testing, the INTRACEPT System with the Flexible Bi-Polar RF Probe and the Access Instruments is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness concerns.