0DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 9, 2016

Relievant Medsystems, Inc.
Mr. Adam Savakus
Executive Vice President
2688 Middlefield Road, Suite A
Redwood City, California 94063

Re: K153272
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: June 8, 2016
Received: June 9, 2016

Dear Mr. Savakus:

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 yours,

Carlos L. Pena -S

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)*
K153272

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.

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."

Premarket Notification 510(k) Summary

Applicant's Name and Address:

Relievant Medsystems, Inc.
2688 Middlefield Road, Suite A
Redwood City, CA 94063

Contact Person: Adam Savakus
Executive Vice President
Telephone: 650-368-1000
Facsimile: 650-298-9205

Date Prepared: July 8, 2016

Device Name:

Device Generic Name: RF Ablation Catheter and Accessories

Device Trade Name: Intracept Intraosseous Nerve Ablation System

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

Predicate Devices:
The Intracept Intraosseous Nerve Ablation System is substantially equivalent to the following legally marketed devices:

Intracept Easy Access Instrument Set and Flexible Bi-Polar RF Probe (K100641)
Stryker RF Coaxial Bipolar Electrodes and Cannulae (K043442)

Device Description:
The Intracept System is comprised of two basic, sterile, single use components, both of which are currently cleared for marketing via 510(k).

- The Intracept Easy Access Instrument Set (*Instrument Set)* is an instrument kit containing trocars, cannulas and guides that provide access to the intended site of radiofrequency (RF) ablation.

- The Intracept Flexible Bi-Polar RF Probe (*RF Probe*) conducts RF energy to the target location.

Additionally, a commercially available, legally marketed RF Generator provides RF energy to the RF Probe. An *Interconnect Cable* is provided to connect the RF Probe to the RF Generator. The only RF Generator currently recommended for use with the Intracept System is the Stockert Neuro N50 (K070336).

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 Instrument Set, a minimally invasive, "transpedicular approach" is used to allow the placement of a cannula into the vertebral body, and a path or channel is created 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 where it enters the vertebral body. This nerve has been identified as a proprioceptive sensory nerve with innervation 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 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.

Substantial Equivalence

Comparison with Predicate Devices

Company and 510(k) Number	**Relievant Medsystems Proposed Device**	**Relievant Medsystems K100641**	**Stryker Instruments K043442**
Description	Intracept Intraosseous Nerve Ablation System (RF Probe and Instrument Set)	INTRACEPT Flexible Bipolar RF Probe and Easy Access Instrument Set	STRYKER RF COAXIAL BIPOLAR ELECTRODES & CANNULAE
Classification	GXI 882.4725 Radiofrequency lesion probe) Class II	GEI 878.4400 Electrosurgical cutting and coagulation device and accessories Class II	GXI 882.4725 Radiofrequency lesion probe) Class II

Technological Characteristics	The Relievant Intracept RF probe is intended to be used with the Stockert Neuro N50 RF Generator. The Stockert N50 is 510(k) cleared as a Neurosurgical generator under GXD for *"Lesioning nerve tissue for functional neurosurgical procedures; or Radiofrequency heat lesion procedures for the relief of pain…" (K070336)* The Flexible RF Probe is a hand held, bipolar single use sterile device that connects to an RF Generator and conducts energy in a controlled manner to the tissue between and around the electrodes. The RF Probe also employs a thermocouple for monitoring and controlling tip temperature. The RF Probe is used with the Easy Access Instrument Set, which allows for the placement of the RF probe into the intended anatomical treatment area.	Identical to the proposed device	The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator (N50), are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facet Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.
Method of Use	Placement of the RF probe at the target; delivery of RF energy into the tissue to achieve tissue ablation (i.e., Cellular necrosis through thermal coagulation)	Identical to the proposed device	Identical to the proposed device
Intended Use	Delivery of RF energy into tissue to ablate tissue and relieve pain	Delivery of RF energy into tissue to coagulate soft tissue	Delivery of RF energy into tissue to ablate tissue and relieve pain

Indication 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 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.	The INTRACEPT Flexible Bipolar RF Probe and Easy Access Instrument Set is intended to be used in conjunction with radiofrequency (RF) generators for the thermal coagulation of soft tissues.	The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF generator, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Non-Clinical Testing (Performance Data)

The Intracept device is identical to the predicate Intracept device. Tests setup and execution were performed in accordance with applicable standards.

Results of the testing demonstrate compliance to the standards, and/or matching the performance of new devices to the predicate device.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Patient contact materials are classified as tissue/bone/dentin < 24hours and tested for compliance to applicable ISO 10993 standards.

The new device is similar in classification, and the materials used in construction are identical to those used in the Intracept predicate device. This table summarizes the biocompatibility testing done and the results.

Intracept RF Probe- Tests	**Test Method Summary**	**Results**
Cytotoxicity	ISO 10993-5:1999 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (MEM Elusion)	PASS (Same materials, same testing as for predicate device.)
Sensitization	ISO 10993-10:2002 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Sensitization)	PASS (Same 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 (Same materials, same testing as for predicate device.)
Intracutaneous Reactivity	ISO 10993-10:2002 – Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (Intracutaneous Reactivity Test: Saline and Cottonseed Oil Extracts)	PASS (Same materials, same testing as for predicate device.)
EtO residuals	ISO 10993-7:2008 – Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals	PASS (Same materials, same testing as for predicate device.)
Intracept Easy Access Instrument Set- Tests	**Test Method Summary**	**Results**

Cytotoxicity	ISO 10993-5:2009 – Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (MEM Elusion)	PASS (Same 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 (Same 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 (Same 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 Test: Saline and Cottonseed Oil Extracts)	PASS (Same materials, same testing as for predicate device.)
EtO residuals	ISO 10993-7:2008 – Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals	PASS (Same materials, same testing as for predicate device.)

Electrical safety testing

The Intracept device is identical in size, materials, construction and used with the same equipment as the Intracept predicate device, therefore the same- IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 test reports are applicable to the subject device. The Intracept RF Probe was evaluated for compliance with the following standards and was found to be in compliance:

IEC 60601-1; Medical electrical equipment; Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2; Medical electrical equipment; Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility

Additional testing also performed as a part of IEC 60601-2-2 for high frequency surgical accessories.

Tests	**Test Method Summary**	**Results**
High frequency surgical accessories	IEC 60601-2-2 Medical electrical equipment Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories: - External Surface Temperature per IEC 60601-1: Third Edition 2012 & IEC 60601-2-2:2009 - Dielectric and Leakage Current per EN 60601-1:2012 & IEC 60601-2-2:2009	PASS (same as for predicate device)

Dimensional and Functional Testing The new device and the Intracept predicate device are identical in size, materials, and construction, and are used with the same RF Generator. The following tests were executed and passed successfully.		
Intracept RF Probe -Tests	**Test Method Summary**	**Results**
Dimensional	Meet dimensional specs per Product Specifications	PASS
Corrosion	Corrosion testing per ISO 10555-1:1995 - Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (Annex A: No visible signs of corrosion)	PASS
Transit	ASTM D4169-09 - Standard Practice for Performance Testing of Shipping Containers and Systems (DC 13, assurance level II)	PASS
Bubble Test	ASTM F 2096-04 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	PASS
Seal Peel Test	ASTM F88/F88M-09 - Standard Test Method for Seal Strength of Flexible Barrier Materials (Seal peel >1.0 lbs)	PASS
Mechanical Testing	Meets all performance specs per Product Specifications; testing includes: - Bend/Buckling (Flexure/Compression) - Handle: Tensile - Distal tip: Tensile	PASS
Sterilization Validation	ISO-11135-2014 - 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
Intracept Easy Access Instrument Set - Tests		
Dimensional	Meet dimensional specs per Product Specifications	PASS
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 D4169-09 - Standard Practice for Performance Testing of Shipping Containers and Systems (DC 13, assurance level II)	PASS
Bubble Test	ASTM F 2096-11 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	PASS

Seal Peel Test	ASTM F88/F88M-09 - Standard Test Method for Seal Strength of Flexible Barrier Materials (Seal peel >1.0 lbs)	PASS
Mechanical Testing	Meets all performance specs per Product Specifications; testing includes: - Introducer Cannula: Tensile & Torque - Trocar: Tensile & Torque - Curved Cannula: Tensile & Torque - J-Stylet: Tensile & Torque - Straight Stylet: Tensile - Stopper Ring: Torque	PASS
Sterilization Validation	ISO-11135-2014 - 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

Interface and Primary Operating Function Testing
The new and the Intracept predicate device are identical. Results of performance testing are summarized below.

Intracept System Tests	**Test Method Summary**	**Results**
Device Compatibility	Probe and Easy Access Instrument Set compatibility specs met per Product Specifications; testing includes: - Dimensional measurements - Performance testing - Simulated use testing Probe and Cable/RFG compatibility specs were met per Product Specifications; testing includes: - Performance testing - Simulated use testing	PASS
Temperature Accuracy	Accuracy verified by measurements and performance testing covering full functional use range	PASS
Lesion	Measured RF Lesion Size in Tissue Model, Bovine In Vivo: - Thermal distribution within vertebral bodies - Lesion size, based on Thermal Dosimetry - Lesion size, based on histological analysis	PASS

Clinical Performance Testing

A Pilot study was performed in seventeen patients, which demonstrated that the Intracept System was effective and safe for treatment of chronic low back pain of at least 6 months duration that had not responded to at least three months of conservative care, and was also accompanied by

either Type 1 or Type 2 Modic changes on an Magnetic Resonance Imaging (MRI) or positive provocative discography.

Based on the results of the pilot study, a pivotal randomized, double-blind, sham controlled clinical study was performed in 225 patients. The results of this study showed that the Intracept System is safe, well-tolerated, and effective for the relief of chronic low back pain of at least 6 months duration that had not responded to at least six months of conservative care, and was also accompanied by either Type 1 or Type 2 Modic changes on an MRI.

Results of the primary end point analysis for the Intent-To-Treat (ITT) population did not show a statistically significant difference between the study arms. While this analysis showed a 19.0 point Least Squares (LS) mean Oswestry Disability Index (ODI) improvement in the Intracept arm, there was a greater than expected response in the Sham arm (Sham ODI LS mean improvement was 15.4 points).

Results of the primary end point analysis for the Per Protocol (PP) population showed that the LS mean improvement in ODI observed in the Intracept arm was statistically superior to the Sham arm (p=0.019). This analysis is a direct comparison of ODI outcomes between the treatment arms in the study population that successfully received the intended therapy per randomization assignment (appropriate ablation of the Basivertebral Nerve (BVN) in the Intracept arm) and completed follow-up per the study protocol (i.e., visit compliant, with no confounding medications or interventions). The results of a 3 Group Model ITT analysis also allowed for a direct comparison of efficacy between patients who received correctly targeted Intracept System treatment (i.e., only patients who received the treatment at the intended location) and patients who received the Sham treatment and demonstrated that the efficacy of the Intracept System is superior to the Sham (p=0.045).

The mean improvement in ODI in the Intracept patients (PP population) at 3 months was 20.5 points; twice the 10-point Minimally Important Clinical Difference (MCID) for ODI as recognized in the published literature. The corresponding mean improvement in ODI in the Sham arm at 3 months was 15.2. See Table 1 below:

Table 1: Primary Analysis: Change from Baseline in Oswestry Disability Index (ODI) at Month 3 (Per-Protocol Population)

	Sham System (N=77)	Intracept System (N=128)	P-Value
Baseline			
ODI Total Score			
N	77	128	
Mean	41.2	42.4	
SD	10.38	10.92	
Median	38.0	39.0	
Min. to Max.	26 to 78	30 to 76	
Month 3			
ODI Total Score			
N	77	128	
Mean	25.8	22.1	

Table 1: Primary Analysis: Change from Baseline in Oswestry Disability Index (ODI) at Month 3 (Per-Protocol Population)

	Sham System (N=77)	Intracept System (N=128)	P-Value
SD	17.44	15.39	
Median	26.0	22.0	
Min. to Max.	0 to 74	0 to 60	
ODI Change from Baseline			
Mean	-15.5	-20.3	
SD	17.87	15.56	
Median	-12.0	-18.0	
Min. to Max.	-62 to 20	-70 to 20	
LS Mean ODI Change from Baseline[a]	-15.2	-20.5	
95% Confidence Interval for LS Mean[a]	[-18.7, -11.7]	[-23.2, -17.8]	
Difference from Sham System in LS Means[a]		-5.3	0.019
95% Confidence Interval for Difference[a]		[-9.8, -0.9]	

[a] Estimates and p-value from ANCOVA (Analysis of Covariance) with factors of treatment group, analysis center and treatment group by analysis center interaction, and a covariate of baseline ODI score.

Note: Last observation carried forward used to impute missing values.

The result for the PP population was sustained through two years of follow-up. Additionally, an analysis of ODI responder rates found that 75.6% of patients treated with the Intracept System demonstrated a greater than 10-point, clinically meaningful improvement in their low back pain and associated disability at 3 months compared to 55.3% in the Sham arm. See Table 2 below:

Table 2: ODI 3-Month Responder Rates (Intent-to-Treat and Per Protocol Populations)

	Intracept System % Responders	**Sham System % Responders**
ITT Population*		
10 point MCID	70.1% (101/144)	54.5% (42/77)
PP Population**		
10 point MCID	75.6% (96/127)	55.3% (42/76)

No imputations for missing data were made.
* 4 patients in the ITT population (3 in the Intracept System arm and 1 in the Sham System arm) had missing ODI scores at the 3-month time point.
**2 patients in the PP population (1 in each arm) had missing ODI scores at the 3-month time point.

Conclusions

Based upon the testing, the Intracept System performs as intended and does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Intracept System is substantially equivalent to these existing devices.