DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 18, 2017

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

Re: K171143
Trade/Device Name: Relievant Medsystems RF Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: July 18, 2017
Received: July 20, 2017

Dear Laurie 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)*
K171143

Device Name
Relievant Medsystems RF Generator (RFG)

Indications for Use *(Describe)*
The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant INTRACEPT Intraosseous Nerve Ablation System 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 18, 2017

Device Name:

Device Generic Name: RF Generator

Device Trade Name: Relievant Medsystems RF Generator™ (Relievant RFG)

Device Classification: II

Classification Name: Radiofrequency lesion generator
21 CFR 882.4400, Product Code GXD

Predicate Devices:

Stockert NEURO N50 Generator: K070336 (primary)
Relievant INTRACEPT Intraosseous Nerve Ablation System: K153272 (reference)

Device Description:

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. RF probes FDA cleared as part of the Relievant INTRACEPT Intraosseous Nerve Ablation System are used with the Relievant RFG.

Indications for Use

The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant INTRACEPT Intraosseous Nerve Ablation System 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

The Relievant RFG and the Stockert NEURO N50 RFG are microcontroller controlled, bipolar RF energy generators intended to delivery RF energy to a targeted site for thermal coagulation. The RFGs include the same indication, have the same intended use, have a similar overall design, and similar operational characteristics. The ablation settings for the Relievant RFG are embedded within the RFG. These embedded settings are a subset of the manually set ablation settings for the primary

predicate device and are the same as the manually set ablation settings for the reference predicate. Differences between the devices do not raise different questions of safety and effectiveness for the subject device. A comparison of the subject to the predicate devices is provided in the table below.

Category	PREDICATE	PREDICATE: Reference	SUBJECT	COMPARISON
	Stockert NEURO N50 Radiofrequency Lesion Generator	**Relievant INTRACEPT Intraosseous Nerve Ablation System**	**Relievant RF Generator**	
510(k)	K070336	K153272	K171143	--
Class	II	II	II	Equivalent
Product Code/Classification	GXD, 882.4400	GXI, 882.4725	GXD, 882.4400	Equivalent
Characteristics:				
Indications For Use	The Stockert NEURO N50 RFG is for general high frequency applications: 1. Radiofrequency heat lesion procedures for the relief of pain, or 2. Lesioning nerve tissue for functional neurosurgical procedures; or	The Relievant 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 Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant INTRACEPT Intraosseous Nerve Ablation System 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. --	Equivalent --

Category	PREDICATE	PREDICATE: Reference	SUBJECT	COMPARISON
	Stockert NEURO N50 Radiofrequency Lesion Generator	**Relievant INTRACEPT Intraosseous Nerve Ablation System**	**Relievant RF Generator**	
	3. Stimulation procedures like provoking stimulation, localized stimulation, blocking stimulation or intraoperative test stimulation.	--	--	--
Anatomical Site	Bone and soft tissue	Bone and soft tissue	Bone and soft tissue	Equivalent
Energy type	Radiofrequency energy	Radiofrequency energy	Radiofrequency energy	Equivalent
Mechanism of action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Equivalent
Operating Mode	Monopolar Bipolar RF energy Neuro-stimulation	-- Bipolar RF energy --	-- Bipolar RF energy --	-- Equivalent --
Output Power	50 W	Not applicable*	20 W	Different
Output Frequency	475kHz	Not applicable*	475kHz	Equivalent
Feedback Mechanism	Power Controlled Temperature Controlled	Not applicable*	-- Temperature Controlled	-- Equivalent
Ablation Settings:	User Set, manual	User Set, manual	Embedded	Equivalent
Temperature	42°C – 100.0°C	85° C	85° C	Equivalent
Temperature Ramp	0 - 50°C /seconds	1°/seconds	1°/seconds	Equivalent
RF Duration	<1 to 16 minutes	15 minutes	15 minutes	Equivalent

*****The INTRACEPT Intraosseous Nerve Ablation System is intended to be used with RF generators; however, a RF generator was not included with the INTRACEPT System cleared.

Non-Clinical Performance Testing

Testing of the Relievant RFG 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 provided in support of the substantial equivalence determination as follows.

Test	Test Method Summary	Results
Electrical	IEC 60601-1-1 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. Complies with the standards.
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. Complies with the standard.
Temperature Accuracy	Verify output temperature 25°C-100°C±1.9°C	Pass

Test	Test Method Summary	Results
RF Output Power	IEC 60601-1-2 Medical electric equipment-Part 1-2: General requirements of safety-Collateral Standard: Electromagnetic compatibility-Requirements and Tests	Pass. Complies with the standard.
Mechanical Testing	IEC 60601-1-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance, 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, as well as Relievant specified requirements.	Pass. Complies with the standards and Relievant requirements.
Software	FDA's May 2005 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for devices designated as a Major Level of Concern	Pass. Met FDA's Guidance requirements for software development documentation and testing.
Other	Programmable Electrical Medical System (PEMS) IEC 62304 Medical Device Software – Software Life-Cycle Processes	Pass. Complies with the standard.
Interface: Usability	FDA Guidance Document: Applying Human Factors and Usability Engineering to Medical Devices, IEC 60601-6 Medical Electrical Equipment – Part 1-6: General Requirements for basic safety and essential performance – Collateral Standard: Usability and IEC 62366 Medical Devices – Part 1: Application of usability engineering to medical devices	Pass. Complies with the standards.

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 Relievant RFG is substantially equivalent to the legally marketed predicate devices 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.