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
Indications for Use

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)
- [x] 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
PRASStaff@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.
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.

<table>
<thead>
<tr>
<th>Category</th>
<th>PREDICATE</th>
<th>PREDICATE: Reference</th>
<th>SUBJECT</th>
<th>COMPARISON</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stockert NEURO N50 Radiofrequency Lesion Generator</td>
<td>Relievant INTRACEPT Intraosseous Nerve Ablation System</td>
<td>Relievant RF Generator</td>
<td></td>
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<tr>
<td>510(k)</td>
<td>K070336</td>
<td>K153272</td>
<td>K171143</td>
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</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>II</td>
<td>II</td>
<td>Equivalent</td>
</tr>
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<td>Product Code/Classification</td>
<td>GXD, 882.4400</td>
<td>GXI, 882.4725</td>
<td>GXD, 882.4400</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>

**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
- 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
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<td>Relevant RF Generator</td>
<td></td>
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<tr>
<td></td>
<td>3. Stimulation procedures like provoking stimulation, localized stimulation, blocking stimulation or intraoperative test stimulation.</td>
<td>--</td>
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</tbody>
</table>

**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  
--  
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  
1⁰/seconds  
1⁰/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 Relevant 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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method Summary</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical</td>
<td>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</td>
<td>Pass. Complies with the standards.</td>
</tr>
<tr>
<td>Temperature Accuracy</td>
<td>Verify output temperature 25°C-100°C+1.9°C</td>
<td>Pass</td>
</tr>
</tbody>
</table>
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.