March 23, 2017

Medtronic Powered Surgical Solutions
Deep Pal
Regulatory Affairs Manager
4620 North Beach Street
Fox Worth, TX 76177

Re: K163182
Trade/Device Name: Medtronic Legend Pneumatic; MR7 Pneumatic; Triton Pneumatic Drill System incorporating various Pneumatic Handpieces; Attachments; Surgical Dissecting Tools; and System Accessories
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBB, KFK, ERL, EQJ, HSZ, GET, HBE, DWH
Dated: December 22, 2016
Received: December 23, 2016

Dear Mr. Pal:

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

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):** K163182

- **Device Name:**
  - Medtronic Legend Pneumatic; MR7 Pneumatic; Triton Pneumatic Drill System incorporating various Pneumatic Handpieces; Attachments; Surgical Dissecting Tools; and System Accessories

**Indications for Use (Describe):**

The Pneumatic Drill System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

Additionally, the Pneumatic Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application of various surgical techniques during the following lumbar spinal procedures:

- Lumbar Microdiscectomy
- Lumbar Stenosis Decompression
- Posterior Lumbar Interbody Fusion (PLIF)
- Transforaminal Lumbar Interbody Fusion (TLIF)
- Anterior Lumbar Interbody Fusion (ALIF)
- Direct Lateral Interbody Fusion (DLIF)

**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)

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*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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SECTION 9: 510(k) SUMMARY

This summary is submitted in accordance with the requirements of 21CFR807.92.

9.1 DATE PREPARED
November 10, 2016

9.2 NAME AND ADDRESS OF MANUFACTURER

Table 4: Manufacturer information

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Establishment Registration Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Powered Surgical Solutions</td>
<td>1625507</td>
</tr>
<tr>
<td>4620 North Beach Street</td>
<td></td>
</tr>
<tr>
<td>Fort Worth, TX 76137 USA</td>
<td></td>
</tr>
<tr>
<td>Medtronic Xomed, Inc.</td>
<td>1045254</td>
</tr>
<tr>
<td>6743 Southpoint Drive North</td>
<td></td>
</tr>
<tr>
<td>Jacksonville, FL 33216 USA</td>
<td></td>
</tr>
</tbody>
</table>

9.3 CONTACT PERSON
Deep Pal
Regulatory Affairs Manager
Telephone: 817.788.6685
Facsimile: 817.788.6222
E-Mail: deep.pal@medtronic.com

9.4 PROPRIETARY NAME
Medtronic Legend Pneumatic, MR7 Pneumatic, Triton Pneumatic Drill System incorporating various Pneumatic Handpieces, Attachments, Surgical Dissecting Tools and System Accessories

9.5 COMMON/USUAL NAME
Surgical Drill Motors and Accessories

9.6 DEVICE CLASSIFICATION NAME

Table 5: FDA device classification information

<table>
<thead>
<tr>
<th>Description</th>
<th>FDA Code</th>
<th>Regulation Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saw, pneumatically powered</td>
<td>KFK</td>
<td>21CFR878.4820</td>
</tr>
<tr>
<td>Motor, drill, pneumatic</td>
<td>HBB</td>
<td>21CFR882.4370</td>
</tr>
<tr>
<td>Drill, surgical, ent (electric or pneumatic) including handpiece</td>
<td>ERL</td>
<td>21CFR874.4250</td>
</tr>
<tr>
<td>Bur, ear, nose and throat</td>
<td>EQJ</td>
<td>21CFR874.4140</td>
</tr>
<tr>
<td>Instrument, surgical, orthopedic, pneumatic powered &amp; accessory/attachment</td>
<td>HSZ</td>
<td>Pre-Amendment</td>
</tr>
<tr>
<td>Pneumatic motor for general surgery</td>
<td>GET</td>
<td>21CFR878.4820</td>
</tr>
<tr>
<td>Drills, burrs, trephines and accessories (simple, powered)</td>
<td>HBE</td>
<td>21CFR882.4310</td>
</tr>
<tr>
<td>Blades, saw, surgical cardiovascular</td>
<td>DWH</td>
<td>21CFR878.4820</td>
</tr>
</tbody>
</table>
9.7 PREDICATE DEVICE IDENTIFICATION

Table 6: Subject Devices that are in the scope of this Submission

<table>
<thead>
<tr>
<th>SUBJECT SYSTEM DESCRIPTION</th>
<th>SYSTEM DESCRIPTION</th>
<th>PREDICATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triton Pneumatic Drill System</td>
<td>Oscillating and Reciprocating Saw Drill-Reamer</td>
<td>K870157</td>
</tr>
<tr>
<td>- Pneumatic Handpiece</td>
<td>- Pneumatic Handpiece</td>
<td>K870157</td>
</tr>
<tr>
<td>- Pneumatic Foot Control Unit</td>
<td>- Pneumatic Control Unit</td>
<td>K870157</td>
</tr>
<tr>
<td>- Surgical Dissecting Tools</td>
<td>- Surgical Dissecting Tools</td>
<td>K870157</td>
</tr>
<tr>
<td>- Attachments</td>
<td>- Attachments</td>
<td>K870157</td>
</tr>
<tr>
<td>- System Accessories</td>
<td>- System Accessories</td>
<td>K870157</td>
</tr>
<tr>
<td>Legend Pneumatic High Speed System</td>
<td>Legend Pneumatic High Speed System</td>
<td>K020069</td>
</tr>
<tr>
<td>- Pneumatic Handpiece</td>
<td>- Pneumatic Handpiece</td>
<td>K020069</td>
</tr>
<tr>
<td>- Pneumatic Foot Control Unit</td>
<td>- Pneumatic Control Unit</td>
<td>K020069</td>
</tr>
<tr>
<td>- Surgical Dissecting Tools</td>
<td>- Surgical Dissecting Tools</td>
<td>K020069, K072315</td>
</tr>
<tr>
<td>- Attachments</td>
<td>- Attachments</td>
<td>K020069</td>
</tr>
<tr>
<td>- System Accessories</td>
<td>- System Accessories</td>
<td>K020069</td>
</tr>
<tr>
<td>Midas Rex MR7 Pneumatic High Speed System</td>
<td>Midas Rex MR7 Pneumatic High Speed System</td>
<td>K090112</td>
</tr>
<tr>
<td>- Pneumatic Handpiece</td>
<td>- Pneumatic Handpiece</td>
<td>K090112</td>
</tr>
<tr>
<td>- Pneumatic Foot Control Unit</td>
<td>- Pneumatic Control Unit</td>
<td>K090112</td>
</tr>
<tr>
<td>- Surgical Dissecting Tools</td>
<td>- Surgical Dissecting Tools</td>
<td>K020069, K072315</td>
</tr>
<tr>
<td>- Attachments</td>
<td>- Attachments</td>
<td>K020069</td>
</tr>
<tr>
<td>- System Accessories</td>
<td>- System Accessories</td>
<td>K090112</td>
</tr>
</tbody>
</table>

9.8 DEVICE DESCRIPTION

The Pneumatic Drill System is a pneumatically powered high-speed drill system consisting of a choice of various Pneumatic Handpieces (comprising of a High Pressure and Exhaust Hose, and Handpiece) equipped with a foot or finger controller, Pneumatic Foot Control Unit, Surgical Dissecting Tools, System Accessories, and where applicable, Attachments to support various Surgical Dissecting Tools, and System Accessories.

The device design, function, the intended use and the general operating principles, and conditions of use of the overall Medtronic Pneumatic Drill Systems remain similar to those cleared under K870157, K020069, K072315, and K090112.

9.9 INDICATIONS FOR USE

The Pneumatic Drill System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

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- Anterior Lumbar Interbody Fusion (ALIF)
- Direct Lateral Interbody Fusion (DLIF)
9.10 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Pneumatically powered drill system, designed to remove soft and hard tissue, and bone, and biomaterials is the technological principle for both the subject and predicate systems.

The subject and predicate systems are based on the following same technological elements:

- Pneumatic Drill System Application: Designed to remove soft and hard tissue, bone, and biomaterials during various surgical applications.
- Operating Principle: The pneumatic energy is supplied to the Handpiece to provide power to operate interchangeable Surgical Dissecting Tools supported by Attachments and intended for use in various surgical procedures to remove soft and hard tissue, bone, and biomaterials.

In terms of the materials used in manufacturing of the patient contacting components of the subject Pneumatic Drill System, the subject Attachments and Surgical Dissecting Tools are similar to the predicate Medtronic Attachments and Surgical Dissecting Tools.

9.11 DISCUSSION OF THE PERFORMANCE TESTING

Testing was completed to ensure the functionality of the Medtronic Pneumatic Drill System for the expanded indications. The following table summarizes the testing completed:

<table>
<thead>
<tr>
<th>TEST</th>
<th>DESCRIPTION</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Literature Review</td>
<td>A comprehensive clinical literature search was conducted and reviewed regarding the safe and effective use of the Drill System for the expanded indications for use, which is the subject of this submission.</td>
<td>The cadaver validation study, and review of supporting literature, supports the use of the Medtronic Drill System in LM, PLIF, TLIF, LSD, ALIF, and DLIF spinal surgical procedures, as well as any variations of these procedures.</td>
</tr>
<tr>
<td>Cadaveric Testing</td>
<td>Users evaluated the acceptability of the subject drill system to its intended use on a variety of procedures using cadavers.</td>
<td>The Medtronic Pneumatic Drill System is acceptable for its intended use in various surgical procedures.</td>
</tr>
</tbody>
</table>

9.12 CONCLUSIONS

The subject Medtronic Pneumatic Drill Systems when compared to the predicate Drill Systems have same intended use, where the subject and the predicate drill systems are intended for use in various surgical procedures to remove soft and hard tissue, and bone, and biomaterials. Results of cadaveric testing have demonstrated that the addition of the proposed indications do not present any new issues of safety or effectiveness, and the systems perform as intended during surgical use, similar to the use during various other surgical procedures on currently cleared indications.