August 14, 2015

Medtronic Xomed, Inc.
Ms. Gabriela Anchondo
Principal Regulatory Affairs Specialist
6743 Southpoint Dr. North
Jacksonville, FL 32216

Re: K150728

Trade/Device Name: XPS Nexus System, XPS Nexus Foot Control, XPS Nexus IV Pole
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL
Dated: July 7, 2015
Received: July 9, 2015

Dear Ms. Anchondo:

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,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
XPS Nexus™ System

Indications for Use (Describe)
The XPS Nexus™ System is indicated for the incision/cutting, removal and drilling of soft and hard tissue and bone in head and neck/ENT, oral/maxillofacial and plastic/reconstructive/aesthetic surgical procedures.

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.

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“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.”
Section 5.0 510(k) Summary

A. 510(k) Owner
Medtronic Xomed, Inc
6743 Southpoint Drive North
Jacksonville, Florida 32216-0980 USA
904-296-9600
904-296-2386 (FAX)

B. Contact Information
Gabriela Anchondo
Regulatory Affairs Manager
Medtronic Xomed, Inc
gabriela.anchondo@medtronic.com

C. Date Summary Prepared
March 19, 2015

D. Proprietary Name
XPS Nexus™ System

E. Device Name

Trade name: XPS Nexus™
Common/Usual Name: Drill, Surgical, ENT (electric or pneumatic) including hand piece (ERL)
Classification Name: Ear, nose and throat electric or pneumatic surgical drill (21 CFR 874.4250, Product Code: ERL, Class II)

F. Predicate Devices:

Trade Name: XPS 3000 System
Common/Usual Name: Drill, Surgical, ENT (electric or pneumatic) including hand piece (ERL)
Classification Name: Ear, nose and throat electric or pneumatic surgical drill (21 CFR 874.4250, Product Code: ERL, Class II)
Premarket Notification: K041413

Trade Name: IPC® Integrated Power Console
Common/Usual Name: Drill, Surgical, ENT (electric or pneumatic) including hand piece (ERL)
Classification Name: Ear, nose and throat electric or pneumatic surgical drill (21 CFR 874.4250, Product Code: ERL, Class II)
Premarket Notification: K081277

G. Device Description

The XPS Nexus™ System is a powered microdebrider and drill system that removes soft tissue, hard tissue and bone during surgical procedures. The system consists of a power control console, a foot control unit and assorted hand-pieces to drive various
burs, blades, drills, rasps and cannulas. Hand-piece options include the StraightShot® M2 Microdebrider, the StraightShot® M4 Microdebrider and the Indigo® Otology Drill.

The power control console also includes integrated irrigation pump for irrigation of blades and burs.

Optional accessories include an IV pole to hold a bag(s) of irrigation solution as well as a carrying case.

**H. Intended Use/Indications for Use:**

The XPS Nexus™ System is indicated for the incision/cutting, removal and drilling of soft and hard tissue and bone in head and neck / ENT, oral / maxillofacial and plastic / reconstructive / aesthetic surgical procedures.
## I. Substantial Equivalence

### Summary of Technological Characteristics

<table>
<thead>
<tr>
<th>Device name</th>
<th>Subject Device</th>
<th>Predicate Device(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The XPS Nexus™ System is indicated for the incision/cutting, removal and drilling of soft and hard tissue and bone in head and neck / ENT, oral / maxillofacial and plastic / reconstructive / aesthetic surgical procedures.</td>
<td>The Electric Drill System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone in Head &amp; Neck / ENT (Otolologic, Neurologic, Neurotologic, Sinus, Rhinologic, Nasopharyngeal / Laryngeal), Oral / Maxillofacial, and Plastic / Reconstructive / Aesthetic Surgical Procedures.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microdebriders</th>
<th>StraightShot™ Magnum II</th>
<th>StraightShot™ M4</th>
<th>StraightShot™ M4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indigo™</td>
<td>Yes</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Visao®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drills</th>
<th>Indigo™</th>
<th>Yes</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visao®</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Basic Features</th>
<th>Hand piece w/suction</th>
<th>Control unit w/Footswitch</th>
<th>1 Irrigation Pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>User interface</td>
<td>Touch pad</td>
<td>Touch screen</td>
<td>Control buttons, displays</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 Irrigation Pumps, 1 optional handpiece cooling pump</td>
</tr>
<tr>
<td>Device name</td>
<td>Subject Device</td>
<td>Predicate Device(s)</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>XPS Nexus™ System</td>
<td>IPC® Integrated Power Console K081277</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>XPS 3000 System K041413</td>
<td></td>
</tr>
<tr>
<td><strong>Provided sterile</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Console/handpiece</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Foot Control</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Blade/bur/drill bit</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Tubing sets</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>Patient contact</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Console/handpiece</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Foot control</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Tubing set (fluid path)</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Blade/bur/drill bit</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>Body contacting materials</strong></td>
<td>Stainless steel and medical polymer</td>
<td>Stainless steel and medical polymer</td>
<td>Stainless steel and medical polymer</td>
</tr>
</tbody>
</table>
J. Testing

The verification and validation testing of the XPS Nexus™ System included the following testing:

**Electrical Safety Testing**

Electrical Safety compliance is demonstrated through testing in accordance with:

<table>
<thead>
<tr>
<th>FDA Recognition Number</th>
<th>Standard Developing Organization</th>
<th>Recognition List Number</th>
<th>Standard Designation Number and Date</th>
<th>Title of Standard</th>
<th>Effective Date</th>
<th>Category</th>
</tr>
</thead>
</table>

Test results indicated that XPS Nexus System complies with the applicable standards.

**Electromagnetic Compatibility Testing**

Electromagnetic Compatibility compliance is demonstrated through testing in accordance with:

<table>
<thead>
<tr>
<th>FDA Recognition Number</th>
<th>Standard Developing Organization</th>
<th>Recognition List Number</th>
<th>Standard Designation Number and Date</th>
<th>Title of Standard</th>
<th>FR Publication Date</th>
<th>Category</th>
</tr>
</thead>
</table>

Test results indicated that XPS Nexus System complies with the applicable standards.
**Software Testing**

Software testing was performed in compliance with the following guidance and standards:

- FDA Guidance: The content of premarket submissions for software contained in medical devices, May 11, 2005
- FDA Guidance: General principles of software validation; Final guidance for industry and FDA staff, January 11, 2002

<table>
<thead>
<tr>
<th>FDA Recognition Number</th>
<th>Standard Developing Organization</th>
<th>Recognition List Number</th>
<th>Standard Designation Number and Date</th>
<th>Title of Standard</th>
<th>FR Publication Date</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-8</td>
<td>IEC</td>
<td>029</td>
<td>62304: 2006-05</td>
<td>Medical device software - Software life cycle processes</td>
<td>08/20/2012</td>
<td>(Software/Informatics)</td>
</tr>
</tbody>
</table>

Test results indicated that XPS Nexus System complies with the applicable standards.

**Performance Testing**

Performance testing was performed in compliance with the following standards:

<table>
<thead>
<tr>
<th>FDA Recognition Number</th>
<th>Standard Developing Organization</th>
<th>Recognition List Number</th>
<th>Standard Designation Number and Date</th>
<th>Title of Standard</th>
<th>FR Publication Date</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-85</td>
<td>IEC</td>
<td>036</td>
<td>60601-1-6 Edition 3.0 2010-01</td>
<td>Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability</td>
<td>07/09/2014</td>
<td>(General I (QS/RM))</td>
</tr>
<tr>
<td>5-67</td>
<td>AAMI ANSI IEC</td>
<td>036</td>
<td>62366:2007/(R)2013</td>
<td>Medical devices - Application of usability engineering to medical devices</td>
<td>07/09/2014</td>
<td>(General I (QS/RM))</td>
</tr>
</tbody>
</table>

Test results indicated that XPS Nexus System complies with the applicable standards.

General performance verification and validation testing of the subject XPS Nexus System was also performed to verify the performance and output characteristics.

No clinical testing was deemed necessary for this Premarket Notification.
K. Conclusion

The data presented in this Premarket Notification support that the subject device is safe and effective and performs in the same manner as the predicate device when used in accordance with the labeled directions for use and for the specified indication(s).

The risks of the subject device, as well as the benefits to the patient, are the same as those attributed to the use of the predicate devices. No new risks have been identified.

The scope of intended use of XPS Nexus™ System is limited as compared with predicate devices; it has the same conditions of use and the same key technological characteristics as predicate devices and does not raise new issues of safety or effectiveness. The XPS Nexus™ System is therefore substantially equivalent to the IPC® Integrated Power Console cleared by K081277 and XPS 3000 System cleared by K041413.