



Food and Drug Administration  
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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

510(k) Number (if known)

K150728

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)

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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## 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<sup>®</sup> M2 Microdebrider, the StraightShot<sup>®</sup> M4 Microdebrider and the Indigo<sup>®</sup> 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<sup>™</sup> 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

	<b>Subject Device</b>	<b>Predicate Device(s)</b>	
<b>Device name</b>	XPS Nexus™ System	IPC® Integrated Power Console K081277	XPS 3000 System K041413
<b>Indications for Use</b>	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.	The Electric Drill System is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone in Head & Neck / ENT (Otologic, Neurologic, Neurotologic, Sinus, Rhinologic, Nasopharyngeal / Laryngeal), Oral / Maxillofacial, and Plastic / Reconstructive / Aesthetic Surgical Procedures.	The XPS 3000 is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery. Otology/ neurotology indications include mastoidectomy, mastoidotomy, and acoustic neuroma. Sinus indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, trans-sphenoidal procedures, maxillary sinus polypectomy, circumferential maxillary antrostomy, choanal atresia, sphenoidotomy, and medial, lateral, and posterior frontal sinusotomy Nasopharyngeal / laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, tonsillectomy, tonsillotomy for obstructive tonsillar disease, removal of endobronchial lesions, and the surgical management of recurrent respiratory papillomatosis (RRP). Head and neck (ENT) indications include soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal and shaping of bone during rhinoplasty procedures, removal of adipose tissue (lipo debridement) in the maxillary and mandibular regions of the face, removal of acoustic neuroma, and incision and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery. The XPS 3000 system using the PowerSculpt handpiece and reciprocating cutting blades / rasps is indicated to cut hard and soft tissue or bone in otorhinolaryngology and head and neck surgery. The XPS 3000 system with reciprocating adapter and suction cannula is intended for the removal of soft tissue and fluid during general surgical procedures including suction lipoplasty for aesthetic body contouring. The XPS 3000 system is indicated for use in orthopedic surgical procedures where the cutting and removal of soft and hard tissue or bone is required. These include spinal and small and large joint arthroscopic procedures. An integral pump is provided for irrigation, and a second integral pump maybe provided for handpiece cooling.
<b>Microdebriders</b>	-	-	-
StraightShot® Magnum II	Yes	Yes	Yes
StraightShot® M4	Yes	Yes	Yes
<b>Drills</b>	-	-	-
Indigo™	Yes	Yes	No
Visao®	No	Yes	Yes
<b>Basic Features</b>	Hand piece w/suction Control unit w/Footswitch 1 Irrigation Pump	Hand piece w/suction Control unit w/Footswitch 2 Irrigation Pumps	Hand piece w/suction Control unit w/Footswitch 1 Irrigation Pumps, 1 optional handpiece cooling pump
<b>User interface</b>	Touch pad	Touch screen	Control buttons, displays

	<b>Subject Device</b>	<b>Predicate Device(s)</b>	
<b>Device name</b>	XPS Nexus™ System	IPC® Integrated Power Console K081277	XPS 3000 System K041413
<b>Provided sterile</b>	-	-	-
Console/handpiece	No	No	No
Foot Control	No	No	No
Blade/bur/drill bit	Yes	Yes	Yes
Tubing sets	Yes	Yes	Yes
<b>Patient contact</b>	-	-	-
Console/handpiece	No	No	No
Foot control	No	No	No
Tubing set (fluid path)	Yes	Yes	Yes
Blade/bur/drill bit	Yes	Yes	Yes
<b>Body contacting materials</b>	Stainless steel and medical polymer	Stainless steel and medical polymer	Stainless steel and medical polymer

## 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:

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	Effective Date	Category
19-4	AAMI ANSI	036	ES 60601-1: 2005/(R)2012 and A1:2012,	<a href="#">C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)</a>	07/09/2014	General II (ES/EMC)

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:

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	FR Publication Date	Category
19-1	IEC	037	60601-1-2 Edition 3: 2007-03	<a href="#">Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests</a>	10/17/2014	General II (ES/EMC)

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
- IEC 60601-1-4 Medical Electrical Equipment, Part 1-4: Collateral Standard: Programmable Electrical Medical Systems; IEC 60601-1-4:1996 (First Ed.) + Am. 1:1999 (Consolidated 1.1 Ed.) for use with IEC 60601-1 (1988), Amts. 1 (1991) and 2 (1995)

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	FR Publication Date	Category
13-8	IEC	029	62304: 2006-05	<a href="#">Medical device software - Software life cycle processes</a>	08/20/2012	(Software/Informatics)

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

## ***Performance Testing***

Performance testing was performed in compliance with the following standards:

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

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.