K081277

# 510(k) Summary

SEP - 5 2008

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|---|---|
| **510(k) Owner** | Medtronic Xomed, Inc<br>6743 Southpoint Drive North<br>Jacksonville, Florida 32216-0980 USA<br>904-296-9600<br>904-296-2386 (FAX) |
| **Contact Name** | Antoine Kouchakjy<br>Senior Regulatory Affairs Specialist<br>Medtronic Xomed, Inc |
| **Date Summary Prepared** | April 15, 2008 |
| **Proprietary Name** | Electric Surgical Drill / Saw System<br>(XPS 4000 System, Midas Rex Legend Drill System, Integrated Power Console (IPC)) |
| **Common Name(s)** | • Drill, Surgical, ENT (electric or pneumatic) including handpiece (ERL)<br>• Saw, Powered, and Accessories (HAB)<br>• Saw, Surgical, ENT (Electric or Pneumatic) (EWQ) |
| **Classification Name(s)** | • Ear, nose, and throat electric or pneumatic surgical drill. (21 CFR 874.4250, Product Code ERL, Class II)<br>• Surgical instrument motors and accessories/attachments (21 CFR 878.4820, Product Code HAB, Class I)<br>• Ear, nose, and throat manual surgical instrument (21 CFR 874.4420, Product Code EWQ, Class I) |

**Marketed device claiming equivalence to**
The electric drill system is equivalent to the Medtronic Xomed XPS system K073255, the Midas Rex Legend EHS system (K935567, K012453, K012456, K012457), and to the Linvatec Advantage Drive Electric System (K002523).

**Device Description**
The electric drill system consists of a power console, footswitches, connection cables, irrigation / cooling tubing sets, a remote irrigation control unit, and assorted handpieces to drive various burs, blades, drills, rasps, and saw blades. The system can also function as an endoscope lens cleaning system.

**Intended Use / Indications for use**
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.

## Summary of Technological Characteristics

| Characteristic | NEW DEVICE (XPS 4000) (Legend EHS System) (Integrated Power Console) | Medtronic Xomed XPS 3000 Electric System (K002224, K010666, K010677, K011321, K041413, K041523, K073255) | Medtronic Powered Surgical Solutions (MPSS) Electric System (K935567, K012453, K012456, K012457) | Linvatec Advantage Drive Electric System (K002523) |
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| Indications for use | 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. | See Next Page | Neurosurgical<br>Spine<br>Orthopedic Surgery<br>General Surgery<br>ENT<br>Maxillofacial<br>Craniofacial | The device functions as a powered instrument system consisting of handpieces to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otlaryngological, Oral / Maxillofacial, Plastic / Reconstructive, and Spinal surgical procedures. |
| Handpieces Compatibility | Drills<br>Microdebriders<br>Saws | Drills<br>Microdebriders<br>- | Drills<br>-<br>- | Drills<br>Microdebriders<br>Saws |
| Pumps used for | Irrigation<br>Motor Cooling<br>Scope Cleaning | Irrigation<br>Motor Cooling<br>- | Irrigation<br>-<br>- | Irrigation<br>Motor Cooling<br>- |
| Stim Guard Capable | Yes | Yes | No | No |
| Provided Sterile | - | - | - | - |
| Console/handpiece | No | No | No | No |
| Foot control | No | No | No | No |
| Tubing sets | Yes | Yes | Yes | Yes |
| Blade/bur/drill bit | Yes | Yes | Yes | Yes |
| Irrigation Remote | Yes | - | - | - |
| Patient Contact | - | - | - | - |
| Console/handpiece | No | No | No | No |
| Foot control | No | No | No | No |
| Tubing set (fluid path) | Yes | Yes | Yes | Yes |
| Blade/bur/drill bit | Yes | Yes | Yes | Yes |
| Irrigation Remote | No | - | - | - |
| External Software Upgradable | Yes | No | No | Unknown |

# XPS 3000 System 510k's

Intended Use

The XPS 3000 system is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.

Indications for use

Otology / neurotology indications include aural atresia, cholesteatoma, cochleostomy, development of a suture tunnel for cochlear implant fixation, drainage of petrous apex cyst from endaural and middle-fossa approach, endolymphatic hydrops, extosis lesion removal, facial nerve decompression, mastoidectomy, mastoidotomy, ossicular chain reconstruction (OCR), otosclerosis, removal of ear tumors including acoustic neuroma, tympanoplasty, and vestibular neurectomy.

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, surgical management of Recurrent Respiratory Papillomatosis (RRP), tonsillectomy, tonsillotomy and removal of endobronchial lesions.

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. An integral pump is provided for irrigation, and a second integral pump may be provided for handpiece cooling.

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.

Neurosurgical procedures where removal and aspiration of soft and hard tissue is desired.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

K081277

SEP - 5 2008

Medtronic Xomed, Inc.
c/o Antoine Kouchakjy
6743 Southpoint Drive, North
Jacksonville, Florida 32216-0980

Re: K081277
Trade/Device Name: Electric Drill System [XPS 4000, Midas Rex EHS System, Integrated Power console]
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 18, 2009
Received: July 21, 2008

Dear Mr. Kouchakjy:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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): K081277

Device Name:
Electric Drill System [XPS4000, Midas Rex EHS system, Integrated Power Console (IPC)]

Indications for Use:

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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K081277