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510(k) Summary

OCT 17 2008

510(k) Owner	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Name	Antoine Kouchakjy Senior Regulatory Affairs Specialist Medtronic Xomed, Inc
Date Summary Prepared	May 20, 2008
Proprietary Name	Electric Surgical Drill / Saw System (XPS 4000 System, Midas Rex Legend Drill System, Integrated Power Console (IPC))
Common Name(s)	• Instrument, Surgical, Orthopedic, AC-Powered Motor and Accessory / Attachment (HWE) • Arthroscope (HRX) • Motor, Drill, Electric (HBC) • Drills,Burrs,Trephines&Accessories(Simple,Powered) (HBE)
Classification Name(s)	• Surgical instrument motors and accessories/attachments (21 CFR 878.4820, Product Code HWE, Class I) • Arthroscope (21 CFR 888.1100, Product Code HRX, Class II) • Electric cranial drill motor (21 CFR 882.4360, Product Code HBC, Class II) • Powered simple cranial drills, burrs, trephines, and their accessories (21 CFR 882.4310, Product Code HBE, Class II)

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, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Medtronic Xomed, Inc.
% Mr. Antoine Kouchakjy
Senior Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K081475
Trade/Device Name: Electric Drill System [XPS4000, Midas Rex EHS system, Integrated Power Console]
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered compound cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBE, HBC, HWE, HRX
Dated: September 15, 2008
Received: September 16, 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): _____

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, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General 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)

Neil R. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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