K111520

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5. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Address of Manufacturer:

Medtronic Xomed, Inc.
6743 Southpoint Drive
Jacksonville, FL 32216
(817) 788-6685 Phone
(817) 788-6222 Facsimile

Establishment Registration Number: 1625507

Contact Person:

Rishi Sinha
Senior Regulatory Affairs Specialist

Date:

Trade or Proprietary Name:

IPC® POWEREASE™ System
IPC System with POWEREASE™
POWEREASE™ System

Common usual or Classification Name:

21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines, and their accessories
21CFR 878.4820 – Surgical instrument motors and accessories/attachments
21CFR882.1870 – Evoked Response Electrical Stimulator

Description:

The purpose of this submission is to add a new driver and an accompanying software module to the IPC®. .The new system is the IPC® POWEREASE™System. The IPC® POWEREASE™ System provides a powered driver that performs multiple functions and also has nerve stimulation capabilities. The IPC® POWEREASE™ System consists of the Integrated Powered Console (K081475, 10/17/2008), a driver handpiece, and cables to connect the driver, IPC® and NIM-ECLIPSE® System together. The driver is powered by the previously cleared Integrated Powered Console equipped with the appropriate software to operate the driver. The driver is used for drilling, tapping and driving screws in the pedicle, placing screws, and driving working end attachments capable of breaking set screw heads, cutting posts, and cutting rods during spinal surgery. The POWEREASE™ Driver also has nerve stimulation capabilities when connected to the Medtronic NIM -ECLIPSE® System (K061113 – 05/23/2006; K061639 - 11/01/2006). An external POWEREASE™NIM Cable that connects the NIM-ECLIPSE® System to the driver enables the driver to have nerve stimulating capability. It should be noted that the IPC® does not provide the stimulation. The stimulation used with the IPC® POWEREASE™ is provided by the Medtronic NIM-ECLIPSE® System.

The driver is equipped with a quick connect feature which allows for easy and secure attachment of different working end attachments compatible with the IPC® POWEREASE™ Driver to perform the various functions mentioned above.

Indications for Use:

The IPC® 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.

The IPC® POWEREASE™ System is indicated for drilling, tapping and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. The IPC® POWEREASE™ System is also used in the placement of screws, or cutting of screws, posts, and rods.

Predicate Device Identification:

The Medtronic IPC® POWEREASE™ System is substantially equivalent to the following predicate devices:

Table 1: Predicate Devices for the IPC® POWEREASE™ System

Device	Manufacturer	510(k) Number	Clearance Date
Integrated Powered Console (Electric Drill System)	Medtronic Xomed, Inc.	K081475	10/17/2008
Stimulating Bur Guard	Medtronic Xomed, Inc.	K063305	11/29/2006
Stryker Consolidated Operating Room Equipment (CORE) System	Stryker Instruments	K032303	1/16/2004
Orthomon	Axon Systems, Inc.	K061113	05/23/2006
Eclipse TCD Neurvascular Workstation	Axon Systems, Inc.	K061639	11/01/2006
XPS 4000 System, Midas Rex Legend EHS System, Integrated Power Console (IPC)	Medtronic Xomed, Inc.	K081277	09/05/2008

Comparison to Predicate Device:

The IPC® POWEREASE™ System is similar in device design, function, intended use and fundamental scientific technology to the previously cleared devices listed above.

Table 2: Comparison of Subject Device to Predicate Device

Features	IPC® POWEREASE™ System	IPC® System (K081475)
Indications	The IPC® 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. The IPC® POWEREASE™ System is indicated for drilling, tapping and driving	The IPC® 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

	screws and working end attachments during spinal surgery, including open and minimally invasive procedures. The IPC® POWEREASE™ System is also used in the placement of screws, or cutting of screws, posts, and rods.	
Handpiece Driver Compatibility	Drills including the POWEREASE™ Driver, Saws, Microdebriders. All Class II devices in the IPC® System other than the POWEREASE™ Driver are cleared via K081475.	Drills, Saws, Microdebriders – All Class II devices cleared via K081475
Nerve Monitoring Capability	Yes – allows for connection to nerve monitoring systems	Yes – allows for connection to nerve monitoring systems

Testing:

Laboratory bench testing conducted on the POWEREASE™ System demonstrates substantially equivalent performance characteristics to the predicate devices currently on the market. Testing was performed according to IEC 60601 Medical Electrical Equipment.

Conclusion/Summary:

Based upon the laboratory bench test summaries, intended use, and the successful completion of design control activities; the IPC® POWEREASE™ System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 6 2011

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

Re: K111520
Trade/Device Name: IPC POWEREASE System
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: Class II
Product Code: HBE, HWE, GWF
Dated: September 29, 2011
Received: October 03, 2011

Dear Mr. Sinha:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin K. Keith

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

Enclosure

4. Indications for Use Statement

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510(k) Number (if known): K111520

Device Name: IPC® POWEREASE™ System

Indications for Use:

The IPC® 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.

The IPC® POWEREASE™ System is indicated for drilling, tapping, and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in the placement of screws, or cutting of screws, posts, and rods.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Ogden for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111520