K123270

510(k) SUMMARY
MEDTRONIC Sofamor Danek
POWEREASE™ System
October 2012

JAN 1 1 2013

I. **Company:**

Medtronic Xomed, Inc. (PowerEase)
Medtronic Surgical Technologies
6743 Southpoint Drive North
Jacksonville, Florida, 32216, USA
(904) 296-9600

Medtronic Sofamor Danek,
USA Inc. (Working Ends)
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Contact:**

Julie Bassett
Principal Regulatory Affairs Specialist
Telephone: (901) 399-3248
Fax: (901) 346-9738

III. **Proprietary Trade Name:**

IPC® System
IPC® POWEREASE™ System
POWEREASE™ System
POWEREASE™ System Working Ends

IV. **Common &Classification Names:**

Powered simple cranial drills, burrs, trephines, and their accessories; Surgical instrument motors and accessories/attachments; Evoked Response Electrical Stimulator

Class:

Class II

Product Code:

HBE, HWE, GWF

V. **Description:**

The POWEREASE™ System Working Ends consists of instruments such as taps, drill bits, screwdrivers, post cutter, set screw break-off tool, reduction nut driver and sleeves. The working ends have a manual alternative. The working ends, listed above, are compatible with the CD HORIZON® SOLERA® and the TSRH® 3Dx

Spinal System implants. Of the working ends, only the taps, screwdrivers, drill bits, and sleeves are also compatible with Medtronic's NIM-ECLIPSE® Spinal System.

VI. 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 or cutting of screws, posts and rods.

VII. Summary of the Technological Characteristics:

The purpose of this application for Premarket Notification is to expand the previously cleared [POWEREASE™ System K111520 (S.E. 10/26/2011)] indications to include placement of not only screws, but rods as well. The indications are changing to include the intended use of the nut reduction driver, as well as, update the indications since screws, posts, and rods may all be "cut" or "placed" during the procedure.

In addition, two modified Taps and a Reduction Nut Driver are being added to the POWEREASE™ System.

The instrument modifications detailed in this submission have no impact on the technological characteristic of the existing instruments. The working end Taps are intended for tapping during spinal surgery, including both open and minimally invasive procedures. The working ends are used to facilitate the placement of the

rods. Like the predicate POWEREASE™ System instruments, the subject instruments are manufactured from stainless steel.

IX. Discussion of Non-Clinical Testing:

Engineering rationales, based on engineering theoretical analysis, were completed using testing that had been performed on the predicate device. The predicate testing was in accordance with IEC 60601 for Medical Electrical Equipment. Information and data to support these engineering rationales, as well as surgeon validations and internal verification activities, were provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

X. Conclusion:

Based on the supporting documentation provided in this premarket notification, Medtronic believes the subject devices demonstrate substantial equivalence to the predicate POWEREASE™ System K111520 (S.E. 10/26/2011).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medtronic Sofamor Danek USA, Incorporated
% Ms. Julie Bassett
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

January 11, 2013

Re: K123270
Trade/Device Name: 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: October 18, 2012
Received: October 19, 2012

Dear Ms. Bassett:

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,

Peter D. Rumm -S

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

Enclosure

510(k) Number (if known): K123270

Device Name: POWEREASE™ System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D. Rumm -S

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123270