October 4, 2018

Medtronic Sofamor Danek USA, Inc.
Ankit Shah
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K182436
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
Dated: September 6, 2018
Received: September 7, 2018

Dear Ankit Shah:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K182436

Device Name
POWEREASE™ System

Indications for Use *(Describe)*

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 placement or cutting of screws, posts and rods.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY
# MEDTRONIC Sofamor Danek
# POWEREASE™ System
# September 2018

**I. Submitter**

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901)396-3133
Fax: (901) 346-9738

**Contact:** Ankit K. Shah
Principal Regulatory Affairs Specialist
Phone: (901) 344-1272

**Date Prepared:** September 4, 2018

**II. Device**

**Name of Device:** POWEREASE™ System

**Classification Names:** Powered simple cranial drills, burrs, trephines, and their accessories (21 CFR 882.4310)
Manual cranial drills, burrs, trephines, and their accessories (21 CFR 882.4300)

**Class:** Class II

**Product Code:** HBE, HBG

**III. Predicate Devices:**

Primary Predicate:

- IPC™ POWEREASE™ SYSTEM, K111520 (S.E. 10/26/2011)

Reference Device:

- CD HORIZON™ Spinal System, K162379 (S.E. 11/16/2016)

*The predicates have not been subject to a design related recall.*

## IV. Description:

The Medtronic Reusable Instruments compatible with Medtronic's IPC™ POWEREASE™ System are spine preparation instruments manufactured from materials commonly used in orthopedic procedures which meet available national or international standards specifications. The instruments may be connected to the POWEREASE™ Driver or used manually. These instruments are also compatible with various Medtronic spinal implant systems.

## V. Indications for Use:

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 placement or cutting of screws, posts and rods.

## VI. Comparison of Technological Characteristics with the Predicate Devices:

The subject working ends for use with the POWEREASE™ System have the same indications, intended use, fundamental scientific technology, materials, and sterilization method as the previously FDA cleared predicate IPC™ POWEREASE™ SYSTEM, K111520 (S.E. 10/26/2011).

## VII. Performance Data:

The following information is provided in support of substantial equivalence.

Biocompatibility

The subject working ends for use with the POWEREASE™ System are limited contact (<24h) external and will be classified as communicating devices with Tissue/Bone/Dentin, according to FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices

Part 1: Evaluation and Testing". The subject instruments are manufactured from identical materials as the predicate devices, in accordance with the following standards:

- ASTM F899: Standard Specification for Wrought Stainless Steels for Surgical Instruments

The mateials used for manufacturing the subject device have a long history of safe and effective use in predicate spinal implants and biocompatibility testing is not required.

Mechanical Testing

Non-clinical mechanical testing was not performed for the subject intrsuments. The subject instruments are identical to the predicate devices in terms of fundamental technology, intended use and indications for use. A confirmatory validation was conducted to ensure that the minor modifications being introduced do not introduce new issues of safety and effectiveness and the devices function as intended. There is no new testing perfomed for the subject devices.

## VIII. Conclusion:

A risk analysis was completed, and the modified subject instruments do not introduce a new worst case. Based on the supporting information provided in this pre-market notification, the subject POWEREASE™ System is substantially equivalent to the predicate IPC™ POWEREASE™ SYSTEM, K111520 (S.E. 10/26/2011).