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 Powered Surgical Solutions
Mr. John Connor
Senior Regulatory Affairs Specialist
Medtronic Navigation
826 Coal Creek Circle
Louisville, Colorado 80027

May 26, 2016

Re: K160713
Trade/Device Name: Stealth-Midas System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 14, 2016
Received: March 15, 2016

Dear Mr. Connor:

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160713

Device Name
Stealth-Midas System

Indications for Use *(Describe)*
The Stealth-Midas System is indicated for the drilling, burring and removal of hard tissue and bone in spinal surgical procedures. Computer-assisted surgery and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

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.

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510(k) Summary

March 14, 2016

I. Company: Medtronic Powered Surgical Solutions
4620 North Beach St.
Fort Worth, TX 76137
Telephone Number: (817) 788-6400

Contact: John Connor
Senior Regulatory Affairs Specialist
Telephone number: (720) 890-2311
Fax: (720) 890-3500
Email: john.m.connor@medtronic.com

II. Proprietary Trade Name: Stealth-Midas System

III. Common Name: Orthopedic Stereotaxic Instrument

IV. Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

V. Classification: Class II

VI. Product Code: OLO

VII. Product Description:

The Stealth-Midas System consists of electric and pneumatic drill handpieces that feature an optical navigation tracker, enabling navigation in conjunction with the StealthStation System. The system allows the navigation of a selection of currently available surgical dissecting tools. The navigated handpieces are provided non-sterile and are reusable.

VIII. Indications for Use:

The Stealth-Midas System is indicated for the drilling, burring and removal of hard tissue and bone in spinal surgical procedures. Computer-assisted surgery and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

IX. Identification of Legally Marketed Devices (Predicate Devices)

- Midas Rex Electric Surgical Drill/Saw System (K081475)
- Midas Rex MR7 Pneumatic High Speed System (K090112)
- Navigated VERTEX SELECT® Instruments (K143628)

X. Comparison of the Technological Characteristics:

The currently available Midas Rex Drill System consists of pneumatic and electric handpieces, attachments, and surgical dissecting tools. There are no changes to any of the attachments or surgical dissecting tools. The only significant difference between the subject navigated handpieces and the currently available handpieces is the addition of a passive optical tracker to the hind to enable navigation of a selection of dissecting tools, and a secondary lock to eliminate any motion of the dissecting tool relative to the optical tracker. The addition of a tracker does not impact the ability of the drill system to perform to their intended use as a drill system.

The passive optical tracking technology is identical to that employed in the use of the predicate navigated Vertex Select instruments. Navigational accuracy testing confirms that the subject navigated drill system is as accurate as the predicate navigated Vertex Select instruments.

XI. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy
CAD Model Evaluation	Verified that the CAD models are accurately reflected in the application software
Formative Usability	Confirmed users can follow the navigated workflow and assemble the device

XII. Conclusions

The Stealth-Midas System has been shown through comparison and testing to be substantially equivalent to the identified predicate devices.