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

March 28, 2017

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

Re: K163565
Trade/Device Name: MR8 Drill System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, HBB, HSZ, ERL, HBE
Dated: December 16, 2016
Received: December 19, 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 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 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" (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 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,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MR8 Drill System

Indications for Use *(Describe)*
The Medtronic MR8 Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial and Craniofacial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

December 19, 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: MR8 Drill System

III. Common Name: Powered Drill System

IV. Classification Name: Motor, Drill, Electric (21 CFR 882.4360)
Motor, Drill, Pneumatic (21 CFR 882.4370)
Drill, Surgical, ENT (21 CFR 874.4250)
Drills, Burs, Trephines & Accessories (21 CFR 882.4310)

V. Classification: Class II

VI. Product Code: HBC, HBB, HSZ, ERL, HBE

VII. Product Description:

The MR8 Drill System consists of electric and pneumatic drill handpieces, attachments, surgical dissecting tools, and system accessories. The handpieces, attachments, and system accessories are provided non-sterile and are reusable. The surgical dissecting tools are provided sterile and are single use.

VIII. Indications for Use:

The Medtronic MR8 Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial and Craniofacial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures.

IX. Identification of Legally Marketed Devices (Predicate Devices)

- Midas Rex Legend EHS Electric Drill System (K081475)

- Midas Rex MR7 Pneumatic High Speed System (K090112)
- Midas Rex Legend System (K020069)

X. Comparison of the Technological Characteristics:

The currently available Midas Rex Drill System consists of pneumatic and electric handpieces, attachments, surgical dissecting tools, and system accessories. The subject drill system remains similar to the predicate drill system in terms of operating principles, where air and/or electric energy is supplied to the handpiece to provide power to operate interchangeable Surgical Dissecting Tools supported by Attachments and intended for use in various surgical procedures to remove soft and hard tissue, bone, and biomaterials. The materials used in design and manufacturing of the drill system remain similar to those of the predicate drill system. Minor design changes were made to the electric/pneumatic handpieces and the attachments to both improve the performance/efficiency of the drill system. None of the changes to the system impact safety and effectiveness or its ability to perform to its intended use as a drill system.

XI. Discussion of the Performance Testing

Testing was completed to ensure the functionality of the new drill system. The following table summarizes the performance testing completed:

Test	Description	Results
Motor Speed/Torque Analysis	Analyzed motor speed/torque profile in comparison to predicate devices	Speed/torque profile is similar to that of predicate Legend device
Drill System Cutting Performance	Cutting performance was compared to predicate drill system in terms of tool chatter and hand vibration	Cutting performance was equivalent or better to that of predicate device
Electrical Safety	Electric powered instruments evaluated for electrical safety	Instruments conform to IEC 60601-1:2005 for electrical safety.
Electromagnetic Compatibility	Electric powered instruments evaluated for electromagnetic compatibility	Instruments conform to IEC 60601-1-2:2014 for electromagnetic compatibility.
Cadaveric Simulated Use	Users evaluated the acceptability of the subject drill system to its intended use on a variety of procedures using cadavers	MR8 Drill System acceptable for its intended use in various surgical procedures

XII. Conclusions

The MR8 Drill System has been shown through comparison and testing to be substantially equivalent to the identified predicate devices.