November 23, 2021

Medtronic Powered Surgical Solutions
Carrie Eddings
Principal Regulatory Affairs Specialist
4620 North Beach Street
Fort Worth, Texas 76137

Re: K213454
Trade/Device Name: Midas Rex MR8 Depth Stop Attachment, Midas Rex MR8 Depth Stop Tool 2.4mm, Midas Rex MR8 Depth Stop Tool 3.2mm, Midas Rex MR8 Depth Stop Tool 3.2mm Long, Midas Rex MR8 Depth Stop Tool 7.5mm
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE, HBB, HBC
Dated: October 22, 2021
Received: October 26, 2021

Dear Carrie Eddings:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213454

Device Name
Midas Rex MR8 Depth Stop Attachment (MR8-ASDS01); Midas Rex MR8 Depth Stop Tool 2. 4mm (MR8-DS1TD24); Midas Rex MR8 Depth Stop Tool 3.2mm (MR8-DS1TD32);Midas Rex MR8 Depth Stop Tool 3.2mm Long (MR8-DS1TD32L); Midas Rex MR8 Depth Stop Tool 7.5mm (MR8-DS1TD75)

Indications for Use *(Describe)*
The Midas Rex MR8 Depth Stop attachment and tools are indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such 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.

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K213454

510(k) Summary

November 23, 2021

Company: Medtronic Powered Surgical Solutions
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Contact: Carrie Eddings (Primary)
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Senior Regulatory Affairs Manager
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Proprietary Trade Name: Midas Rex MR8 Depth Stop Attachment and Tools
Common Name: MR8 Depth Stop System
Classification Name: Powered cranial drills, burrs, trephines, and their accessories (21 CFR 882.4310)
Classification: Class II
Product Code: HBE
Primary Predicate: Midas Rex Legend Depth Stop Attachment and Tools, K191597

Product Description:
The Midas Rex MR8 Depth Stop attachment and tools are intended to create a cranial access hole of a known diameter and depth.

Indications for Use:
The Midas Rex MR8 Depth Stop attachment and tools are indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such procedures.

Comparison of the Technological Characteristics:
There have been no significant changes to the Midas Rex™ Legend Depth Stop Attachment and Tools since prior clearance in K191597.

The subject device, Midas Rex™ MR8™ Depth Stop Attachment and Tools, are to be used with the MR8™ High-Speed Drill Systems and the Stealth Autoguide™ System to create

cranial access holes of specific diameter and depth as previously cleared through K191597 for the Midas Rex™ Legend Depth Stop Attachment and Tools.

Changes from the predicate include:

- Compatibility with the predicate MR8 Drill Systems included within K181535
- Extended depth setting to 20mm
- Minor modifications to tool head geometry
- Adding a new task in the user workflow

Feature	Subject Device (Midas Rex™ MR8™ Depth Stop System)	Predicate Device (Midas Rex™ Legend™ Depth Stop System, K191597)	Equivalence Discussion
Sponsor	Medtronic Powered Surgical Solutions	Medtronic Powered Surgical Solutions	**Identical**
Product Code	HBE	HBE, HBC, HBB	**Identical**
Drill System Operating Principle	• Pneumatic • Electric	• Pneumatic • Electric	**Identical**
Intended Use	The Midas Rex MR8 Depth Stop system is intended to create a cranial access hole of a known diameter and depth.	The Midas Rex Legend Depth Stop system is intended to create a cranial access hole of a known diameter and depth.	**Identical**
Indications for Use	The Medtronic Midas Rex MR8 Drill System is indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such procedures.	The Medtronic Midas Rex Legend Drill System is indicated for the incision, cutting, removing, and drilling of soft and hard tissue during cranial surgical procedures with the intent to create a hole through the cranium to allow surgeons access to desired surgical locations and/or to facilitate insertion, placement of other surgical devices during such procedures.	**Identical**
System components	• Electric Handpieces • Pneumatic Handpieces • Attachments • Surgical Dissecting Tools	• Electric Handpieces • Pneumatic Handpieces • Attachments • Surgical Dissecting Tools	**Identical**
Patient Contacting Components	• Attachments • Surgical Dissecting Tools	• Attachments • Surgical Dissecting Tools	**Identical**
Attachment Materials	Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Polymeric	Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Polymeric	**Identical**
Attachment Configuration	Straight, Variable	Straight, Variable	**Identical**

Feature	Subject Device (Midas Rex™ MR8™ Depth Stop System)	Predicate Device (Midas Rex™ Legend™ Depth Stop System, K191597)	Equivalence Discussion
Attachment Tube Length	12.8cm (tube retracted) 14.5cm (tube exposed)	13.7cm (tube retracted) 14.8cm (tube exposed)	**Equivalent** The attachment tube length is inherent due to the overall design of MR8 attachments and does not impact the performance or safety of the device.
Sterilization Method – Reusable Attachment	Steam	Steam	**Identical**
Surgical Dissecting Tool Materials	Tool Steel	Tool Steel	**Identical**
Dissecting Tool Tip Style	Twist Drill	Twist Drill	**Equivalent** Minor tool tip modifications which do not impact safety or performance.
Dissecting Tool Overall Length	17-22cm	17-22cm	**Identical**
Dissecting Tool Head Diameter	2.1 – 7.5 mm	2.1 – 7.5 mm	**Identical**
Packaging – Sterile Dissecting Tools	Individually packaged in a clear plastic capped tube placed within a polypoly pouch	Individually packaged in a clear plastic capped tube placed within a polypoly pouch	**Equivalent** The packaging is identical except for the tube cap. On the predicate device it is yellow, and on the subject device, the tube cap is blue.
Sterilization Method – Single Use Tools	Gamma with minimum radiation dose of 25 kGy	Gamma with minimum radiation dose of 25 kGy	**Identical**
Shelf Life – Dissecting Tools	5 Years	5 Years	**Identical**

Discussion of the Performance Testing:
The intended use of the subject devices, Midas Rex™ MR8™ Depth Stop Attachments and Tools and predicate are identical, and their technological characteristics are similar. The subject devices are a line extension to the MR8 Drill System (K183515) in the same way that the predicate device was a line extension to the Legend Drill Systems (K163182 and K170312). The changes from the predicate, do not raise any new issues of safety and effectiveness.

Risk management was conducted in accordance with ISO 14971:2019 and did not identify any new risks when compared to the predicate. The following testing was conducted to demonstrate that the modifications to the subject devices are as safe and effective as the predicate.

- Product Life Verification
- Summative Validation
- Biocompatibility Testing

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use, indications for use and support a determination of substantial equivalence.

Conclusions
The Midas Rex™ MR8™ Depth Stop Attachment and Tools have shown through comparison to be substantially equivalent to the identified predicate devices.