November 2, 2020

Medtronic Powered Surgical Solutions (MPSS)
Jainam Shah
Sr Regulatory Affairs Specialist
4620 North Beach Street
Fort Worth, Texas 76137

Re: K202552
Trade/Device Name: Midas Rex Attachments and Dissecting Tools
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 2, 2020
Received: September 3, 2020

Dear Jainam 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/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,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K202552

Device Name
Midas Rex™ attachments and dissecting tools

Indications for Use *(Describe)*
The Midas Rex™ attachments and dissecting tools for Mazor are indicated for the incision/cutting, drilling, burring, and removal of hard tissue and bone in open and minimally invasive spine procedures.

Computer-assisted surgery and its associated applications are intended as an aid for locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition for 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.

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510(k) Summary

September 02, 2020

I. Company: Medtronic Powered Surgical Solutions
4620 North Beach Street
Fort Worth, Texas 76137
Telephone Number: (720) 890-3200

Contact: Jainam Shah
Sr. Regulatory Affairs Specialist
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Jenna Groves (Alternate)
Regulatory Affairs Manager
Telephone number: (817) 788-6686
Email: jenna.a.groves@medtronic.com

II. Proprietary Trade Name: Midas Rex™ Attachments and Dissecting tools

III. Common Name: Orthopedic Stereotaxic Instrument

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

V. Classification: Class II

VI. Product Code: OLO

VII. Predicate Devices
The legally marketed predicate devices are identified below:

Predicate	510(k) Clearance
Primary Predicate MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools	K183515 S.E. 12-May-2019
Additional Predicate: Stealth Midas MR8™ System	K183644 S.E. 22-May-2019

VIII. Product Description:

Midas Rex™ attachments and surgical dissecting tools for Mazor are intended for the incision/cutting, drilling, burring, and removal of hard tissue and bone. The subject instruments are designed to be utilized through a cannula, for use with the Mazor X Stealth Edition™ system in open and minimally invasive spine procedures.

The subject devices perform the intended function as part of the existing Medtronic Midas Rex™ surgical drill systems which consist of the subject attachments and dissecting tools, electric and pneumatic drill handpieces and system accessories.

IX. Indications for Use:

The Midas Rex™ attachments and dissecting tools for Mazor are indicated for the incision/cutting, drilling, burring, and removal of hard tissue and bone in open and minimally invasive spine procedures.

Computer-assisted surgery and its associated applications are intended as an aid for locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition for 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.

X. Comparison of the Technological Characteristics:

The subject Midas Rex™ attachments and dissecting tools utilize the same fundamental scientific technology and have the same mode of operation and functionality as the predicate attachments and surgical dissecting tools (K183515), i.e. they are powered by the existing electric/pneumatic handpieces for the intended use. The subject devices have equivalent materials and sterilization/reprocessing methods as the primary predicate (K183515). The changes in design features between the subject and the predicates do not raise any new risks or any concerns about the safety and effectiveness. The subject navigated devices have an integrated optical tracker to enable real-time navigation in a manner identical to the additional predicate Stealth Midas™ MR8™ (K183644). The subject navigated devices also meet the established system-level navigation accuracy requirements.

Table 1: Comparison of technological characteristics

Feature	**Subject Devices (Midas Rex™ attachments and surgical dissecting tools)**	**Primary Predicate Midas MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools (K183515)**	**Additional Predicate Stealth Midas™ MR8™ (K183644)**
Regulation	21 CFR 882.4560 (Stereotaxic Instrument)	21 CFR 882.4360 (Motor, Drill, Electric) 21CFR 882.4370 (Motor, Drill, Pneumatic)	21 CFR 882.4560 (Stereotaxic Instrument)

Feature	**Subject Devices (Midas Rex™ attachments and surgical dissecting tools)**	**Primary Predicate Midas MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools (K183515)**	**Additional Predicate Stealth Midas™ MR8™ (K183644)**
		21 CFR 882.4310 (Drills, Burs, Trephines & Accessories	
Product Code	OLO	HBC, HBB, HBE	OLO, HAW
Intended Use	Incision/cutting, drilling, burring, and removal of hard tissue and bone.	Incision / cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials.	Incision / cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials.
Indications for Use	The Midas Rex™ attachments and dissecting tools for Mazor are indicated for the incision/cutting, drilling, burring, and removal of hard tissue and bone in open and minimally invasive spine procedures. Computer-assisted surgery and its associated applications are intended as an aid for locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition for 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.	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. Additionally, the MR8 Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application of various surgical techniques during the following lumbar spinal procedures: • Lumbar Microdiscectomy • Lumbar Stenosis Decompression • Posterior Lumbar Interbody Fusion (PLIF) • Transforaminal Lumbar Interbody Fusion (TLIF) • Anterior Lumbar Interbody Fusion (ALIF) • Direct Lateral Interbody Fusion (DLIF) The Midas Rex MR8 ClearView Tools are used only in conjunction with the MR8 Drill System to perform as intended. Please refer to the	The Stealth-Midas MR8™ System is indicated for the drilling, burring and removal of hard tissue and bone in spinal and cranial 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.

Feature	Subject Devices (Midas Rex™ attachments and surgical dissecting tools)	Primary Predicate Midas MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools (K183515)	Additional Predicate Stealth Midas™ MR8™ (K183644)
		Midas Rex MR8 Drill System and associated User's Guides for the Indications of Use	
General System Components	• Attachments - Guided and Navigated w/ optical tracker • Surgical Dissecting Tools • System Accessories	• Electric Handpieces • Pneumatic Handpieces • Attachments • Surgical Dissecting Tools • System Accessories	• Electric Handpieces w/ optical tracker • Pneumatic Handpieces w/ optical tracker • Attachments • Surgical Dissecting Tools • System Accessories
Materials	Attachments: Stainless Steel Tracker: Aluminum, Stainless Steel Surgical Dissecting Tools: Tool (M2) Steel	Attachments: Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Torlon 4301 Surgical Dissecting Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride	Attachments - Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Polymeric Surgical Dissecting Tools - Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Tracker: Aluminum
Surgical Dissecting Tool Tip Style	Twist Drill	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw, Reverse Taper	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw, Reverse Taper
Surgical Dissecting Tool Overall Length	23cm 31cm	3 – 42 cm	3-42 cm
Surgical Dissecting Tool Head Diameter	3.0 mm	0.5 – 25 mm	0.5 – 25 mm
Attachment Configuration	Straight	Straight, Angled, Variable, Double-Lock, Footed, Telescoping, Perforator, Jacobs Chuck, J-Latch, Contra Angle, Metal Cutting	Straight, Angled, Variable, Double-Lock, Footed, Telescoping, Perforator, Jacobs Chuck, J-Latch, Contra Angle, Metal Cutting

Feature	**Subject Devices (Midas Rex™ attachments and surgical dissecting tools)**	**Primary Predicate Midas MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools (K183515)**	**Additional Predicate Stealth Midas™ MR8™ (K183644)**
Attachment Length	23 cm 31cm	2 – 40 cm	2 – 40 cm
Drill System Operating Principle	• Pneumatic (powered by Pneumatic Pressure) • Electric (powered by IPC)	• Pneumatic (powered by Pneumatic Pressure) • Electric (powered by IPC)	• Pneumatic (powered by Pneumatic Pressure) • Electric (powered by IPC)
Packaging – Sterile Surgical Dissecting Tools	Individually packaged in a clear plastic capped tube placed within a poly-poly pouch	Individually packaged in a clear plastic capped tube placed within a poly-poly pouch	The Surgical Dissecting Tools are individually packaged in a clear plastic capped tube placed within a poly-poly pouch.
Sterilization Method – Single Use Tools	Gamma with minimum radiation dose of 25 kGy	Gamma with minimum radiation dose of 25 kGy	Gamma with minimum radiation dose of 25 kGy
Sterilization Method – Reusable Attachment	Steam	Steam	Steam
Shelf Life – Surgical Dissecting Tools	5 Years	5 Years	5 Years
Navigation Optical Tracking Principle	Optical (Infra-red)	N/A	Optical (Infra-red)
System level Navigation Accuracy Acceptance Criteria	Mean Positional Error (mm) ≤ 2.0 mm Mean Trajectory Error (degrees): ≤ 2.0 degrees	N/A	Mean Positional Error (mm) ≤ 2.0 mm Mean Trajectory Error (degrees): ≤ 2.0 degrees
System level Navigation Accuracy Values	Mean Positional Error (mm): 1.12 mm Mean Trajectory Error (degrees): 0.37 degrees	N/A	Mean Positional Error (mm): 0.94 mm Mean Trajectory Error (degrees): 0.85 degrees

XI. Discussion of the Performance Testing:

Testing conducted to demonstrate equivalency of the subject device to the predicate devices is summarized as follows:

Performance Testing Activity	Description
Functional and Reliability Design Verification	Demonstrates the ability of the Midas Rex™ attachment and dissecting tools to perform throughout a single procedure and throughout expected product life thus, verifying the design robustness.
Navigational Accuracy Analysis	Provides confirmation that the subject devices satisfy the necessary navigational accuracy requirements.
CAD Model Analysis	Verifies the correctness of CAD model representations of the subject devices for the Mazor X Stealth Edition™ system.
Human Factors/ Usability Testing	Demonstrates that the usability and human factors considerations were adequately addressed and validated, and the product design performs according to its intended use.

The subject devices met the appropriate requirements and passed all the performance testing activities listed above. Additionally, biological endpoint testing, conducted per recommendations from ISO 10993-1:2018, indicates that the subject devices are non-cytotoxic, non-sensitizing, non- irritating, non-toxic, non-pyrogenic, non-hemolytic and pose a negligible risk of adverse biological effects to patients when used as intended.

XII. Conclusions

The subject devices have shown through comparison to be substantially equivalent to the identified predicate devices.