May 12, 2019

Medtronic Powered Surgical Solutions
Jenna Groves
Regulatory Affairs Manager
4620 North Beach Street
Fort Worth, Texas 76137

Re: K183515
Trade/Device Name: MR8 Drill System, Midas Rex MR8 ClearView Tools
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, HBB, HBE, ERL, HSZ
Dated: April 11, 2019
Received: April 12, 2019

Dear Jenna Groves:

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 Krueger, M.S.E.
Assistant Director
Neurosurgical Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183515

Device Name
MR8 Drill System
Midas Rex MR8 ClearView Tools

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.

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 Midas Rex MR8 Drill System and associated User's Guides for the Indications of Use.

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

December 13, 2018

I. Company:

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

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

II. Proprietary Trade Name:
MR8™ Drill System
Midas Rex™ MR8™ ClearView™ Tools

III. Common Name:
Powered Drill System
Dissecting tool - Powered Simple cranial bur

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 Codes:
HBC, HBB, HSZ, ERL, HBE

VII. Product Description:
The Medtronic MR8™ Drill System is comprised of both Electric and Pneumatic powered, rotary cutting handpieces, attachments, surgical dissecting tools, and accessories designed to remove soft and hard tissue, bone, and biomaterials during various surgical procedures. The surgical dissecting tools are provided sterile and are single use, while the rest of the system components are provided non-sterile and are reusable.

The Midas Rex™ MR8™ ClearView™ Tools are designed to interface with Midas Rex™ MR8 Drill System motor to support bone and tissue removal during surgical

procedures. The Midas Rex™ MR8™ ClearView™ Tools are part of a larger portfolio of tools and accessories designed to be used with the Midas Rex™ MR8 System/Platform.

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.

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 Midas Rex MR8 Drill System and associated User's Guides for the Indications of Use.

IX. Summary of the Technological Characteristics

See Table 3-1: MR8 Drill System and Midas Rex MR8 ClearView Tools as compared to Primary Predicate Devices

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
Product Code	HBC, HBB, HBE, ERL, HSZ	HBC, HBB, HBE, HSZ, ERL	HBE, HBC, HRX, HWE, EQJ, ERL, KFK	KFK, HBB, ERL, EQJ, HSZ, GET, KFK, HBE, DWH	Similar.
Intended Use	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.	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.	Identical.
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. 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 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.	The Medtronic Electric Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) including craniotomy; as well as Ear, Nose and Throat (ENT), Orthopedic, Arthroscopic, Spinal, and General Surgical Procedures including Maxillofacial, Craniofacial and Sternotomy Surgeries. Additionally, the Electric 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:	The Medtronic Pneumatic Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) including craniotomy; as well as Ear, Nose and Throat (ENT), Orthopedic, Arthroscopic, Spinal, and General Surgical Procedures including Maxillofacial, Craniofacial and Sternotomy Surgeries. Additionally, the Pneumatic 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:	Similar. The Indications of Use for the MR8 Drill System are consolidated as shown. The subject devices of Midas Rex™ MR8™ ClearView™ Tools are used with the MR8™ Drill system. The proposed indications do not present any new issues of safety or effectiveness, given the minor differences between MR8 Drill System and Electric and Pneumatic Drill Systems that were

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
	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 Midas Rex MR8 Drill System and associated User's Guides for the Indications of Use.		• 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)	• 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)	previously cleared under K163565.
General System Components for the Drill System	Electric Handpiece, Pneumatic Handpiece Attachments, Surgical Dissecting Tools, System Accessories	Electric Handpiece, Pneumatic Handpiece, Attachments, Surgical Dissecting Tools, System Accessories	Electric Handpiece, Attachments, Surgical Dissecting Tools, System Accessories	Pneumatic Handpiece, Attachments, Surgical Dissecting Tools, System Accessories	Similar. The subject devices Midas Rex™ MR8™ ClearView™ Tools are used with the MR8 Drill System but replace "Attachments" and

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
					"Surgical Dissecting Tools" as one single Curved Bur with the key subassemblies.
Patient Contacting Components	Attachments and Surgical Dissecting Tools Midas Rex™ MR8™ ClearView™ Tools	Attachments and Surgical Dissecting Tools	Attachments and Surgical Dissecting Tools Surgical Curved Burs	Attachments and Surgical Dissecting Tools Curved Burs	Similar. The subject devices Midas Rex™ MR8™ ClearView™ Tools are used with the MR8 Drill System but replace "Attachments" and "Surgical Dissecting Tools" as one single Curved Bur with the key subassemblies.
Materials of Patient Contacting Components	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 Midas Rex™ MR8™ ClearView™ Tools:	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	Attachments - Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Torlon 4301 Dissecting Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Surgical Curved Burs: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Coating;	Attachments - Stainless Steel, Aluminum, Ceramic, Phenolic, Epoxy, Chrome Coated Brass, Polymeric Dissecting Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Surgical Curved Burs: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Coating;	Similar The materials of patient contacting components between the subject devices and Predicate devices remain similar.

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
	Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Coating; Curved Tube: Stainless Steel; Bushing/Bearing Retainers: Stainless Steel; Hub: Polymeric; Bushing Insert, Cooling Sleeve: Polymeric; Lubricant: Nyogel;		Curved Tube: Stainless Steel; Bushing/ Bearing Retainers: Stainless Steel; Hub: Polymeric; Bushing Insert Cooling Sleeve: Polymeric; Lubricant: Nyogel; and Adhesive: Cyanoacrylate	Curved Tube: Stainless Steel; Bushing/Bearing Retainers: Stainless Steel; Hub: Polymeric; Bushing Insert Cooling Sleeve: Polymeric; Lubricant: Nyogel; and Adhesive: Cyanoacrylate	
Surgical Dissecting Tools – Tip Style	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 Tapered	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw, Reverse Tapered	Round/Acorn, Match Head, Ball, Cylinder, Oval, Tapered/Side Cutting, Metal Cutting, Twist Drill, Hole Maker/Saw, Reverse Tapered	Similar. The subject device Tip designs remains similar to the predicate device Tip designs. Any new addition of Tools to the product family are designed and manufactured within the predicate range of tip designs.
Surgical	Surgical Dissecting Tool:	Surgical Dissecting	Surgical Dissecting Tool:	Surgical Dissecting Tool:	Similar.

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
Dissecting Tool - Overall Length	3-42 cm Midas Rex™ MR8™ ClearView™ Tools: 5-14 cm	Tool: 3-42 cm	3-42 cm Surgical Curved Bur: 9-14 cm	3-42 cm Surgical Curved Bur: 9-11 cm	The overall length of the subject devices remains within the range of length previously cleared for the predicate devices.
Surgical Dissecting Tool - Head Diameter	Surgical Dissecting Tool: 0.5 mm - 25 mm Midas Rex™ MR8™ ClearView™ Tools: 0.5 mm – 4.5 mm	Surgical Dissecting Tool: 0.5 mm - 25 mm	Surgical Dissecting Tool: 0.5-25 mm Surgical Curved Bur: 1-4 mm	Surgical Dissecting Tool: 0.5-25 mm Surgical Curved Bur: 1-4 mm	Similar. The head diameter of the subject devices remains within the range of diameter previously cleared for the predicate devices.
Attachment Configuration	Straight, Angled, Variable, Double-Lock, Footed, Telescoping, Perforator, Jacobs Chuck, J-Latch, Metal Cutting Not Applicable to Midas Rex™ MR8™ ClearView™ Tools	Straight, Angled, Variable, Double-Lock, Footed, Telescoping, Perforator, Jacobs Chuck, J-Latch, Metal Cutting	Straight, Angled, Footed, Contra Angled, Right Angled, Metal Cutting, Depth limiting Drill Guides, Perforator, Jacob Chuck Attachments, Wire/Pin Collet Attachments	Straight, Angled, Footed, Contra Angled, Right Angled, Metal Cutting, Depth limiting Drill Guides, Perforator, Jacob Chuck Attachments, Wire/Pin Collet Attachments	Similar. The subject devices Midas Rex™ MR8™ ClearView™ Tools are used with the MR8 Drill System but replace "Attachments" and "Surgical Dissecting Tools" as one single Curved Bur with the key subassemblies.
Attachment Length	2-40 cm Not Applicable to Midas Rex™ MR8™ ClearView™ Tools	2-40 cm	2-40 cm	2-40 cm	Similar. The subject devices Midas Rex™ MR8™ ClearView™ Tools are used with the MR8 Drill System

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
					but replace "Attachments" and "Surgical Dissecting Tools" as one single Curved Bur with the key subassemblies.
Drill System Operating Principle	Electric powered by IPC and Pneumatic powered by Pneumatic Pressure	Electric powered by IPC and Pneumatic powered by Pneumatic Pressure	Electric powered by IPC	Pneumatic powered by Pneumatic Pressure	Similar. The drill system operating principle is similar to the predicate devices.
Packaging – Single Use Dissecting Tools	The Surgical Dissecting Tools are individually packaged in a clear plastic capped tube placed within a poly-poly pouch. Midas Rex™ MR8™ ClearView™ Tools: Sterile Tools are individually packaged into a Tyvek Envelope and sealed. The sealed pouch is individually packaged into a shipping carton.	The Surgical Dissecting Tools are individually packaged in a clear plastic capped tube placed within a poly-poly pouch.	The Surgical Dissecting Tools are individually packaged in a Propionate cellulosic plastic capped tube and sealed within a 4 mil PET-Nylon-HDPE Co-Ex (Peel Seal)/4 mil PET-Nylon-EVA Pouch. Curved Burs: Sterile Curved Burs are individually packaged into a Tyvek Envelope and sealed. The sealed pouch is individually packaged into a shipping carton.	The Surgical Dissecting Tools are individually packaged in a Propionate cellulosic plastic capped tube and sealed within a 4 mil PET-Nylon-HDPE Co-Ex (Peel Seal)/4 mil PET-Nylon-EVA Pouch. Curved Burs: Sterile Curved Burs are individually packaged into a Tyvek Envelope and sealed. The sealed pouch is individually packaged into a shipping carton.	Similar. The Packaging of the subject devices remains similar as compared to the Predicate devices.
Sterilization	Surgical Dissecting Tools and Midas Rex™ MR8™ ClearView™ Tools are supplied Gamma Sterilized Non-sterile (Handpieces, Attachments, System	Sterile (Surgical Dissecting Tools) Non-sterile (Handpieces, Attachments, System Accessories)	Surgical Dissecting Tools & Curved Burs are supplied Gamma Sterilized; - Electric Handpieces, and Attachments are supplied Non-Sterile and require cleaning and sterilization prior to each	Surgical Dissecting Tools & Curved Burs are supplied Gamma Sterilized; - Pneumatic Handpieces, and Attachments are supplied Non-Sterile and require cleaning and sterilization prior to each surgical use;	Similar. The Sterilization of the subject devices remains similar as compared to the Predicate devices.

Feature/ Attribute	Subject Devices (MR8™ Drill System and Midas Rex™ MR8™ ClearView™ Tools)	MR8 Drill System (K163565)	Electric Drill Expanded (K170312)	Pneumatic Drill Expanded (K163182)	Selection Rationale
	Accessories)		surgical use; - Electric Foot Control Unit, and System Accessories are supplied Non-Sterile.	- Pneumatic Foot Control Unit, and System Accessories are supplied Non-Sterile.	
Shelf Life	5 years for Surgical Dissecting Tools 4 years for Midas Rex™ MR8™ ClearView™ Tools	5 years for Surgical Dissecting Tools	5 years for Surgical Dissecting Tools 4 years for Curved Burs	5 years for Surgical Dissecting Tools 4 years for Curved Burs	Similar. The shelf life of the subject device is similar to the predicate devices.

X. Identification of Legally Marketing Devices

- MR8 Drill System (K163565)
- IPC Systems, Legend EHS Handpieces And Legend Stylus Touch Handpiece, Microsaw Handpieces, Triton Electric High Torque Handpiece, Attachments And Surgical Dissecting Tools (K170312)
- Medtronic Legend Pneumatic; MR7 Pneumatic; Triton Pneumatic Drill System Incorporating Various Pneumatic Handpieces; Attachments; Surgical Dissecting Tools; And System Accessories (K163182)

XI. Discussion of the Performance Testing

There has been no additional testing performed on the MR8™ Drill System as there are no design changes.

Testing was completed to ensure the functionality of Midas Rex™ MR8™ ClearView™ Tools with the MR8™ Drill system. The following table summarizes the performance testing completed:

Test	Description	Results
Tool Chatter and Hand Vibration	Compared the vibration characteristics between the subject devices and their equivalent predicates	Tool Chatter and Hand Vibration for subject devices scored similar and/ or better than the equivalent Predicates
Irrigation Rate vs IPC Setting	Compared Irrigation Rate on the IPC against the actual occurrence	Irrigation Rate delivered by the subject devices was found to be the same or more than the one displayed on the IPC
Thermal Performance	Evaluated the integrity of the subject devices through respective duty cycles and the corresponding thermal performance	The subject devices completed their respective duty cycles intact. The maximum temperature reached by the subject devices was below the burn threshold.

XII. Conclusions

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

The Midas Rex™ MR8™ ClearView™ Tools have the same intended use, and have shown through comparison and testing to be substantially equivalent to the identified predicate devices.