



May 15, 2017

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medtronic Powered Surgical Solutions
% Xiaojian Sun
Sr. Regulatory Affairs Specialist
Medtronic Neurosurgery
125 Cremona Dr.
Goleta, California 93117

Re: K170312

Trade/Device Name: IPC Systems, Legend EHS Handpieces and Legend Stylus Touch Handpiece, Microsaw Handpieces, Triton Electric High Torque Handpiece, Attachments and Surgical Dissecting Tools

Regulation Number: 21 CFR 882.4360

Regulation Name: Electric Cranial Drill Motor

Regulatory Class: Class II

Product Code: HBC, HBE, HRX, HWE, EQJ, ERL, KFK

Dated: January 31, 2017

Received: February 1, 2017

Dear Xiaojian Sun:

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,


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

Indications for Use

510(k) Number (if known)
K170312

Device Name

IPC Systems, Legend EHS Handpieces and Legend Stylus Touch Handpiece, Microsaw Handpieces, Triton Electric High Torque Handpiece, Attachments and Surgical Dissecting Tools

Indications for Use (Describe)

The Electric Drill System is a electrically operated surgical instrument system. The electric motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications 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:

- 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)

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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SECTION 9: 510(k) SUMMARY

This summary is submitted in accordance with the requirements of 21CFR807.92.

9.1 DATE PREPARED

January 31, 2017

9.2 NAME AND ADDRESS OF MANUFACTURER

Table 4: Manufacturer information

Establishment Name	Establishment Registration Number
Medtronic Powered Surgical Solutions 4620 North Beach Street Fort Worth, TX 76137 USA	1625507
Medtronic Xomed, Inc. 6743 Southpoint Drive North Jacksonville, FL 33216 USA	1045254

9.3 CONTACT PERSON

Xiaojian Sun
Senior Regulatory Affairs Specialist
Telephone: 805.571.8758
E-Mail: xiaojian.sun@medtronic.com

9.4 PROPRIETARY NAME OF THE PROPOSED DEVICES

IPC Systems, Legend EHS Handpieces and Legend Stylus Touch Handpiece, Microsaw Handpieces, Triton Electric High Torque Handpiece, Attachments and Surgical Dissecting Tools

9.5 COMMON/USUAL NAME

Surgical Drill Motors and Accessories

9.6 DEVICE CLASSIFICATION NAME

Table 5: FDA device classification information

Description	FDA Code	Regulation Number
Drills, burrs, trephines and accessories (simple, powered)	HBE	21CFR882.4310
Motor, drill, electric	HBC	21CFR882.4360
Arthroscope	HRX	21CFR888.1100
Instrument, surgical, orthopedic, ac-powered motor and accessory/attachment	HWE	21CFR878.4820
Bur, ear, nose and throat	EQJ	21CFR874.4140
Drill, surgical, ent (electric or pneumatic) including handpiece	ERL	21CFR874.4250
Saw, pneumatically powered	KFK	21CFR878.4820

9.7 PREDICATE DEVICE IDENTIFICATION

Table 6: Subject Devices that are in the scope of this Submission

SUBJECT SYSTEM DESCRIPTION	PREDICATE	
	SYSTEM DESCRIPTION	510(k) NUMBER
Medtronic Electric Drill System	Electric Drill System [XPS 4000 System, Midas Rex Legend EHS System, IPC]	K081475
- IPC (Integrated Power Console)	- IPC (Integrated Power Console)	K081475
- Legend EHS Handpieces	- Legend EHS Handpieces	K081475, K012457
- Legend Stylus Touch Handpiece	- Legend Stylus Touch Handpiece	K081475, K012457
- Microsaw Handpieces and Blades	- Microsaw Handpieces and Blades	K081475
- Surgical Dissecting Tools	- Surgical Dissecting Tools	K020069
- Surgical Dissecting Tools (Curved Bur)	- Surgical Dissecting Tools (Curved Bur)	K072315
- Legend Attachments	- Legend Attachments	K020069
- Electric Foot Pedal and Y-Splitter	- Electric Foot Pedal and Y-Splitter	K081475
- Irrigation Tubing Sets	- Irrigation Tubing Sets	K081475
- System Accessories	- System Accessories	K081475
Triton Electric High Torque Handpiece	Triton Electric High Torque Handpiece	K121264
- Triton Electric High Torque Handpiece	- Triton Electric High Torque Handpiece	K121264
- Surgical Dissecting Tools	- Surgical Dissecting Tools	K121264, K870157
- Attachments	- Attachments	K121264, K870157
- System Accessories	- System Accessories	K121264, K870157
Legend Electric High Speed Drill System	Legend Electric High Speed Drill System	K012457
- Electric Handpiece	- Electric Handpiece	K081475, K012457
- Surgical Dissecting Tools	- Surgical Dissecting Tools	K020069
- Surgical Dissecting Tools (Curved Bur)	- Surgical Dissecting Tools (Curved Bur)	K072315
- Legend Attachments	- Legend Attachments	K020069

9.8 DEVICE DESCRIPTION

The Electric Drill System consists of an electric Integrated Power Console, Electric Foot Control unit with Y-Splitter, Connection Cables, Irrigation/Cooling Tubing Sets including a remote Irrigation Control Unit, and various Electric Handpieces and/or electric motors and Attachments to drive various Surgical Dissecting Tools. The Integrated Power Console device of the Electric Drill System can also function as an endoscope lens cleaning system.

The device design, function, the intended use and the general operating principles, and conditions of use of the overall Medtronic Electric Drill System remain similar to those cleared under K012457, K081475, and K121264.

The surgical dissecting tools and attachments remain similar to those covered under K870157, K020069, and K072315.

9.9 INDICATIONS FOR USE

The Electric Drill System is a electrically operated surgical instrument system. The electric motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications 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:

- 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)

9.10 COMPARISON OF INTENDED USE

The expanded indication of the subject device did not alter the intended use of the device, which is to remove soft and hard tissue, bone, and biomaterials during surgical procedures. The cadaveric study demonstrated that the addition of the proposed indications do not present any new issues of safety or effectiveness, and the systems perform as intended during surgical use, similar to the use during other various surgical procedures on currently cleared indications. Therefore it is concluded that the subject device has the same intended use as the predicate device.

9.11 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Electrically powered drill system, designed to remove soft and hard tissue, and bone, and biomaterials is the technological principle for both the subject and predicate systems.

The subject and predicate systems are based on the following same technological elements:

- Electric Drill System Application: Designed to remove soft and hard tissue, bone, and biomaterials during various surgical applications.
- Operating Principle: The 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.

In terms of the materials used in manufacturing of the patient contacting components of the subject Electric Drill System, the subject Attachments, Surgical Dissecting Tools, and irrigation tubing sets are similar to the predicates.

9.12 DISCUSSION OF THE PERFORMANCE TESTING

TEST	DESCRIPTION	RESULTS
Clinical Literature Review	A comprehensive clinical literature search was conducted and reviewed regarding the safe and effective use of the Electric Drill System for the expanded indications for use, which is the subject of this submission.	The review of supporting literature supports the use of the Medtronic Electric Drill System in LM, PLIF, TLIF, LSD, ALIF, and DLIF spinal surgical procedures, as well as any variations of these procedures.

Cadaveric Testing	Users evaluated the acceptability of the subject electric drill system to its intended use on a variety of procedures using cadavers.	The Medtronic Electric Drill System is acceptable for its intended use in various surgical procedures.
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9.13 CONCLUSION

The subject Medtronic Electric Drill Systems when compared to the predicate Drill Systems have same intended use, where the subject and the predicate drill systems are intended for use in various surgical procedures to remove soft and hard tissue, and bone, and biomaterials. Results of cadaveric testing have demonstrated that the addition of the proposed indications do not present any new issues of safety or effectiveness, and the systems perform as intended during surgical use, similar to the use during various other surgical procedures on currently cleared indications.