DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 7, 2017

Ad-tech Medical Instrument Corporation
% Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K170442
Trade/Device Name: Cranial Drill Bits and Accessories
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBE, HBG
Dated: August 7, 2017
Received: August 10, 2017

Dear Mr. Syring:

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 (DICE) 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 (DICE) 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

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)*
K170442

Device Name
Cranial Drill Bits and Accessories

Indications for Use *(Describe)*
The Cranial Drill Bits and accessories are intended to be used for drilling holes in the skull for neurological procedures, such as brain biopsy, brain contacting electrode and electrode accessory device placement.

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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5.0 510(k) Summary – K170442

This summary is provided to support the 510(k) pre-market notification for the Cranial Drill Bits and accessories.

Company Name:	Ad-Tech Medical Instrument Corporation 1901 William Street Racine, WI 53404 Phone: (262) 634-1555
Company Contact:	Lisa Theama, Chief Operating Officer
Date Summary Prepared:	August 3, 2017
Trade Name:	Cranial Drill Bits and Accessories
Common Name:	Cranial Drill Bits
Classification Name:	21 CFR 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories, Product Code: HBE, Class II 21 CFR 882.4300 Manual cranial drills, burrs, trephines, and their accessories, Product Code: HBG, Class II
Predicate Devices:	K062842 Twist Drills (Bits), Primary Predicate K122456 MRI Cranial Drill K160129 MRII Cranial Drill and Accessories

5.1 Product Description

The device under review is a family of cranial drill bits and accessories. These cranial drill bits and accessories are applied to create a hole through the skull in support of neurological procedures.

Cranial drill bits are twist drill bits used for drilling holes in the skull, supporting access to the brain for brain biopsy, brain contacting electrode placement, electrode accessory placement such as Anchor Bolts or other needs as determined by the user. The cranial drill bit variations are 16 cm to 30 cm length and 2.4 mm to 3.2 mm outer diameter.

Accessories to the cranial drill bits include:

- Drill Stop: A collar placed on the outer diameter of the drill bit to provide a depth placement indicator.
- Drill Stop Wrench: The Drill Stop Wrench attaches the Drill Stop to the cranial drill bit.
- Drill Sleeve Guide: The Drill Sleeve Guide is an optional accessory, consisting of a hollow tube of stainless steel that the cranial drill bit passes through to minimize the wobble of the drill bit as it is passed to the skull. The Drill Sleeve Guide is placed within a stereotactic frame.
- Guide Block: A Guide Block is an optional accessory that adapts to a stereotactic frame to hold the Drill Sleeve Guide.

5.2 Indications for Use

The Cranial Drill Bits and accessories are intended to be used for drilling holes in the skull for neurological procedures, such as brain biopsy, brain contacting electrode and electrode accessory device placement.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison the Cranial Drill Bits and accessories to the predicate devices applied to support this pre-market notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	Cranial Drill Bits and Accessories (Under Review)	Twist Drills (Primary Predicate K062842)	MRI Cranial Drill (Predicate K122456, K160129)	Comment
Intended use	The Cranial Drill Bit and Accessories are used with drills for creating a hole in the skull to provide access or placement of accessory components.	The Twist Drill Bit and Accessories are used with drills for creating a hole in bone to provide access or placement of hardware.	The Cranial Drill Bit and Accessories are used with drills for creating a hole in the skull to provide access.	Same
Indications for Use	The Cranial Drill Bits and accessories are intended to be used for drilling holes in the skull for neurological procedures, such as brain biopsy, brain contacting electrode and electrode accessory device placement.	The Lorenz Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.	The MRII Cranial Drill and accessories is intended to provide access through the skull for ventriculostomy or other neurological procedures, such as biopsy or catheter placement, in or near an MR scanner of 3T maximum field strength. The MRI Cranial Drill and accessories are intended to be used only when the scanner is not performing a scan. The MRII Cranial Drill is intended for single use only.	The drill bits create an access hole in the skull to support neurological procedures.
Cranial drill bit diameter	2.4 mm to 3.2 mm	0.7 mm to 2.4 mm	2.0 mm to 3.2 mm	Equivalent
Cranial Drill Bit Accessories	Yes Drill Stop Drill Stop Wrench Drill Sleeve Guide Guide Block	Yes Drill Sleeve Guide	Yes Lancet Depth Stop, Guard (Drill Stop) Ruler	Equivalent The accessories are optional and may be used to support stereotactic use of the cranial drill bit.
Provided Sterile	Yes (Option: Drill Bit, Drill Stop, Drill Stop Wrench)	No	Yes	Equivalent

Table 5.3-1: Substantial Equivalence Technical Characteristics				
Feature	**Cranial Drill Bits and Accessories (Under Review)**	**Twist Drills (Primary Predicate K062842)**	**MRI Cranial Drill (Predicate K122456, K160129)**	**Comment**
Single patient use, Disposable	Yes (Drill Bit, Drill Stop, Drill Stop Wrench)	Yes	Yes	Equivalent
Reusable	Accessory Guide Block and Sleeve Guide	No applicable	No applicable	Qualification of user applied reusable processes
Environment of Use	Intraoperative	Intraoperative	Intraoperative	Same
Duration of Use	< 1 Minute	< 1 Minutes	< 1 Minutes	Same
Patient contact material	Stainless Steel	Stainless Steel	Stainless Steel	Same
Drill Diameters	2.4 mm to 3.2 mm	0.7 mm to 2.4 mm	2.0 mm to 3.2 mm, 3.2mm to 6.0 mm	Equivalent
Sterilization Method (when supplied sterile)	Ethylene Oxide process	Not applicable, Not supplied sterile	Ethylene Oxide process	Same

5.4 Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the cranial drill bits and accessories, evaluations were conducted to confirm compliance with performance requirements, including:

Test	**Summary of Requirement**	**Result**
Drilling efficiency	Drill through simulated skull material in < 1 min.	Pass
Drill bit run-out ("wobble") *Test with Guide Block, Drill Sleeve Guide and Drill Stop.*	Comparison of drilled hole diameter to the desired hole size.	Pass
Drill bit run-out ("wobble") *Test with-out Guide Block, Drill Sleeve Guide and Drill Stop.*	Comparison of drilled hole diameter to the desired hole size.	Pass
Mechanical compatibility	Guide Block compatible with stereotactic frame	Pass

5.5 Conclusion

The cranial drill bits and accessories meet performance requirements equivalent to the predicates. The intended use and technology of the cranial drill bits and accessories are the same as the predicate devices.