August 9, 2018

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

Re: K181544
Trade/Device Name: Anchor bolt (as an accessory to Depth Electrodes)
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: June 8, 2018
Received: June 12, 2018

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. 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,

Jay R. Gupta -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)*
K181544

Device Name
Anchor Bolts as Accessories to Depth Electrodes

Indications for Use *(Describe)*
The Ad-Tech Anchor Bolts are optional accessories for use with Depth Electrodes. The Anchor Bolts may be applied when it is desired to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the electrode.

Anchor Bolts are secured in the skull to provide an access point for Depth Electrodes.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary

This summary is provided to support the 510(k) pre-market notification for the Anchor Bolts, as accessories to Depth Electrodes.

Company Name:	Ad-Tech Medical Instrument Corporation 400 West Oakview Parkway Oak Creek, WI 53154 Phone: (262) 634-1555
Company Contact:	Lisa Theama, Chief Operating Officer
Date Summary Prepared:	June 8, 2018
Trade Name:	Anchor Bolts
Common Name:	Anchor Bolt (Accessory to Depth Electrodes)
Classification Name:	Depth Electrode 21 CFR 882.1330 Product Code: GZL Class II
Predicate Device:	K970418 Anchor Bolt, Accessory Depthalon® Depth Electrode PMT Corporation

5.1 Product Description

The device under review is a family of Anchor Bolts. Anchor Bolts are optional accessories to Depth Electrodes. These Anchor Bolts provide an optional access point through the skull and stabilization support for Depth Electrodes.

5.2 Intended Use of the Device

The Ad-Tech Anchor Bolts are optional accessories for use with Depth Electrodes. The Anchor Bolts may be applied when it is desired to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the electrode.

Anchor Bolts are secured in the skull to provide an access point for Depth Electrodes.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison of the Anchor Bolts to the predicate device applied to support this pre-market notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics			
Feature	**Anchor Bolts (Under Review)**	**Anchor Bolt, Accessory Depthalon® Depth Electrode (Predicate K970418)**	**Comment**
Indications for Use	The Ad-Tech Anchor Bolts are optional accessories for use with Depth Electrodes. The Anchor Bolts may be applied when it is desired to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the electrode. Anchor Bolts are secured in the skull to provide an access point for Depth Electrodes.	The PMT depth electrode anchor bolt is an accessory used in cases where it is necessary to minimize concerns about potential cerebrospinal fluid leakage and infection of the subdural space will stabilizing the electrode during intraoperative electro clinical characterization. The PMT depth electrode anchor bolts rest on the skull with the insertion of the anchor bolt tapered screw threads into a predrilled burr hole through a skin incision.	Same. Both Anchor Bolts are applied to a pre-drilled hole in the skull. The Anchor Bolts support Depth Electrode placement.
Clinical Application	Threaded into a pre-drilled hole in the skull.	Threaded into a pre-drilled hole in the skull.	Same
Duration of use	< 30 days	< 30 days	Same
Contra-indications	Anchor Bolts should not be used on any patient whom the physician/ surgeon considers at risk for infection or on whom the use cannot be performed safely. The Anchor Bolt should not be used with patients that have softening of the skull or low skull bone density.	Depthalon® Depth Electrodes should not be used in the presence of any infection of the scalp. Other infections may be considered a contraindication if determined by the attending physician. The Anchor bolt accessory should not be used if the patient has a softening of the skull or low skull bone density.	Equivalent Anchor Bolts are selected and applied by a physician knowledgeable in their use.
Anchor Bolt Single patient use, Disposable	Yes	Yes	Same
Provided Sterile	Yes (Anchor Bolts provided sterile, optional for Placement/Removal Wrench)	Yes (Anchor bolts can be provided sterile or non-sterile)	Equivalent
User Sterilizable	Yes (Placement/Removal Wrench only)	Yes (Anchor Bolts supplied non-sterile)	As a convenience to the user, the Placement / Removal Wrench can be re-sterilized.
Environment of Use	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations	Same
Duration of Use	< 30 days	< 30 days	Same
Patient contact material	Titanium Silicone (inner lumen gasket) Parylene	Titanium Alloy Silicone (inner lumen gasket)	Equivalent
Length	13 mm to 26 mm	25 mm to 40 mm	Equivalent

Table 5.3-1: Substantial Equivalence Technical Characteristics			
Feature	**Anchor Bolts (Under Review)**	**Anchor Bolt, Accessory Depthalon® Depth Electrode (Predicate K970418)**	**Comment**
			The length of the Anchor Bolt is based upon need and user preferences.
Compatible Depth Electrode Body Diameter	0.86 mm to 1.3 mm	1.27 mm	Equivalent
Depth Electrode Retention Force	> 100 grams	> 100 grams	Same
Placement / Removal Wrench	Yes	Unknown	Given the unique design of Anchor Bolts it is very likely that the predicate device requires a placement and removal tool. Hand tightening an Anchor Bolt into a pre-drilled skull hole is not probable.

5.4 Non-clinical Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the Anchor Bolts, evaluations were conducted to confirm compliance with performance requirements, including:

Test	Test Method Summary	Result
Torque required to insert to pre-drilled skull hole.	With a torque wrench, verify the torque required to insert the Anchor Bolt into pre-drilled hole in 40 pcf polyurethane foam (simulated skull bone) with the Placement/Removal Wrench is ≤ 8 in-lbs. (N=10 samples).	Pass All results ≤ 1 in-lbs.
Axial tension to pull Anchor Bolt out of pre-drilled skull hole.	With a tensile tester, measure the axial tension to pull the Anchor Bolt out of a pre-drilled hole in 40 pcf polyurethane foam is ≥ 40 lbf. (N=10 samples)	Pass All results > 48 lbf.
Axial tension to pull Depth Electrode from the Anchor Bolt.	With a tensile tester, measure the axial tension to pull a Depth Electrode from the Anchor Bolt, ≥ 100 grams. (N=10 samples).	Pass All results > 140 grams.
Anchor Bolt gasket resist CSF leakage.	Insert Depth Electrode into the Anchor Bolt secured in 40 pcf polyurethane foam. Apply a metal tube with a diameter larger than the Depth Electrode and Anchor Bolt body, around both. Seal the metal tube to the polyurethane foam. Fill the metal tube with water to a hydrostatic pressure of	Pass No leaks observed

Test	Test Method Summary	Result
	15 mmHg. Verify no leakage at the Depth Electrode, Anchor Bolt after 24 hours. (N=22 samples)	after 24 hours.
Sterility	Anchor Bolts and Placement/Removal Wrenches are terminally ethylene oxide sterilized devices by a validated EtO sterilization cycle, per ANSI/AAMI/ISO 11135-1:2007 half-cycle method. The sterility assurance level (SAL) is ≤ SAL of 10^{-6}.	Pass
Sterile barrier integrity	The sterile barrier package is a double Tyvek pouch. The methods applied to evaluate the Tyvek sterile barrier package integrity included post terminal sterilization: simulated distribution, seal peel and bubble emission testing.	Pass
Anchor Bolt silicone gasket shelf life	The ability of real time aged Anchor Bolts with Silicone Gaskets to meet Depth Electrode retention requirements and minimize cerebrospinal fluid (CSF) leakage were evaluated to the methods above for Axial tension to pull Depth Electrode from the Anchor Bolt and Anchor Bolt gasket resist CSF leakage.	Pass The same acceptance criteria were met.
Biocompatibility	The following test methods were applied to final finished form Anchor Bolts (patient contacting materials), with passing results: • Cytotoxicity: L929 MEM Elution Test – ISO • Sensitization: Kligman Maximization Test – ISO • Intracutaneous Reactivity: Intracutaneous Injection Test - ISO • Acute Systemic Toxicity: 28-Day Systemic Toxicity in Rabbits via Subcutaneous Implantation • Material-Mediated Pyrogenicity: Rabbit Pyrogen Test (Material Mediated) - ISO • Genotoxicity: Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay - ISO and Mouse Lymphoma Mutagenesis Assay - ISO • Hemocompatibility: Rabbit Blood Hemolysis Test (Indirect Contact) – ASTM • Neurotoxicity by: SK-N-MC MEM Elution Test. • Subacute / Subchronic Toxicity: Systemic Injection Test - ISO • Implantation: Neurological (Brain) Implantation Test – ISO.	Pass

5.5 Conclusion

The Anchor Bolts meet performance requirements equivalent to the predicate device. The intended use and technology of the Anchor Bolts are the same as the predicate device.