May 18, 2023

Ad-Tech Medical Instrument Corporation
% Linford Leitch
Regulatory Consultant
NAMSA Medical Research Organization
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K223276
Trade/Device Name: Anchor Bolts as Accessories to Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: April 17, 2023
Received: April 18, 2023

Dear Linford Leitch:

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,

Patrick Antkowiak -S

Patrick Antkowiak
Acting Assistant Director
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)*
K223276

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5 510(k) Summary

a. Company Name, Address:
Ad-Tech Medical Instrument Corporation
400 West Oakview Parkway
Oak Creek, WI 53154

b. Contact:
Brendan McCrea
Chief Technology Officer
400 West Oakview Parkway
Oak Creek, WI 53154
Email: bmccrea@adtechmedical.com
Phone: (262) 634-1555 x1100

c. Official Correspondent:
Linford Leitch
Regulatory Consultant
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

d. Date prepared
October 21, 2022

e. Subject Device

Device Name:	Anchor Bolts
Device Classification Name:	Electrode, Depth
Regulation Number:	21 CFR
Common Name:	Anchor Bolt (Accessory to Depth Electrode)
Device Class:	Class II
Classification Product Code:	GZL
Regulation Medical Specialty:	Neurology
510(k) Review Panel:	Neurology

f. Predicate Device

The Anchor Bolt is substantially equivalent to:

510(k) Number:	K181544
Device Name:	Anchor Bolt
Applicant:	Ad-Tech Medical Instrument Corporation
Device Classification Name:	Electrode, Depth
Regulation Number:	21 CFR 882.1330
Common Name:	Anchor Bolt (Accessory to Depth Electrode)
Device Class:	Class II
Classification Product Code:	GZL
Regulation Medical Specialty:	Neurology
510(k) Review Panel:	Neurology

g. Device 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.

h. Intended Use / 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.

i. Statement of Substantial Equivalence

Table 1: Comparison Anchor Bolts **-** Features of the Anchor Bolts are detailed below:

j. Comparison Table

Table 1: Comparison Anchor Bolts

Feature	**Anchor Bolts (Under Review)**	**Anchor Bolts K181544**	**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 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.	Same
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	

Feature	Anchor Bolts (Under Review)	Anchor Bolts K181544	Comment
Contraindications	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.	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.	Same
Anchor Bolt Single patient use, Disposable	Yes	Yes	Same
Provided Sterile	Yes (Anchor Bolts provided sterile, optional for Placement/Removal Wrench)	Yes (Anchor Bolts provided sterile, optional for Placement/Removal Wrench)	Same
User Sterilizable	Yes (Placement/Removal Wrench only)	Yes (Placement/Removal Wrench only)	Same
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	TitaniumSilicone (inner lumen gasket) Parylene	TitaniumSilicone (inner lumen gasket) Parylene	Same
Length	13 mm to 26 mm	13 mm to 26 mm	Same
Compatible Depth Electrode Body Diameter	0.86 mm to 1.3 mm	0.86 mm to 1.3 mm	Same
Depth Electrode Retention Force	> 100 grams	> 100 grams	Same
Placement / Removal Wrench	Yes	Yes	Same
MR Labeling	MR Conditional	Safety in MRI Not Evaluated	Substantially Equivalent
MR Labeling does not raise any questions of the safety and effectiveness of the device because performance testing was completed to evaluate MR conditional parameters. The Anchor Bolts labeling has been updated with MR Conditional use information.			

k. Performance Data

Ad-Tech, in conjunction with University of Houston, has conducted performance evaluations of the Anchor Bolts to address hazards in the MR environment. As per the Guidance: *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued May 20, 2021, for passive devices, evaluations were conducted for image artifact, magnetically induced displacement force, magnetically induced torque and RF induced heating. Results of the testing allow the device to be labeled MR Conditional and the results summaries follow.

Table 2: 1.5T Test Result Summary

Hazard Addressed	Test Method Used	Acceptance Criterion	Medical Device Configuration Tested	Summary of Test Results and pass/fail if Appropriate
Image Artifact	ASTM F2119-13	No Criteria, Descriptive Statement	Device with the maximum mass/linear length	Adoption from 3.0T tests since 3.0T is the worst-case.
Magnetically Induced displacement force	ASTM F2052-15	<45° deflection	The device with maximum mass	Adoption from 3.0T tests since 3.0T is the worst-case.
Magnetically Induced Torque	ASTM F2213-17, Low friction surface method	<45° rotation	The device with maximum mass	Adoption from 3.0T tests since 3.0T is the worst-case.
RF Induced Heating	ASTM F2182-19e2	<6°C	Based on the ISO10974 methodology and devices with different lengths, different electrode designs, and different insertion depths were studied.	Under the condition defined in the labeling, the MR induced heating will be less than <6°C

Table 3: 3.0T Test Result Summary

Hazard Addressed	Test Method Used	Acceptance Criterion	Medical Device Configuration Tested	Summary of Test Results and pass/fail if Appropriate
Image artifact	ASTM F2119-13	No Criteria, Descriptive Statement	Device with the maximum mass/linear length	Image distortion of 19 mm from the edge of the device
Magnetically Induced Displacement Force	ASTM F2052-15	<45° deflection	The device with maximum mass	pass
Magnetically Induced Torque	ASTM F2213-17, Low friction surface method	<45° rotation	The device with maximum mass	pass
RF Induced Heating	ASTM F2182-19e2	<6°C	Based on the ISO10974 methodology and devices with different lengths, different electrode designs, and different insertion depths were studied.	Under the condition defined in the labeling, the MR induced heating will be less than <6°C

l. 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.