May 18, 2023

Ad-Tech Medical Instrument Corporation
% Marcella Martin
Senior Regulatory Consultant
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K223269
Trade/Device Name: Spencer Probe Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: Class II
Product Code: GZL
Dated: April 16, 2023
Received: April 18, 2023

Dear Marcella Martin:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223269

Device Name
Depth Electrodes (Spencer Probe Depth Electrode)

Indications for Use *(Describe)*
The AD-TECH Depth Electrodes (Spencer Probe Depth Electrodes) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

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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5 510(k) Summary

a. Company Name, Address:
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c. Official Correspondent:
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NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

d. Date prepared
October 21, 2022

e. Subject Device

Device Name:	Depth Electrodes (Spencer Probe Depth Electrode)
Device Classification Name:	Electrode, Depth
Regulation Number:	21 CFR 882.1330
Common Name:	Depth Electrode
Device Class:	Class II
Classification Product Code:	GZL
Regulation Medical Specialty:	Neurology
510(k) Review Panel:	Neurology

f. Predicate Device

The Ad-Tech Depth Electrodes is substantially equivalent to:

510(k) Number:	K163355
Device Name:	Depth Electrodes (Depth Electrodes, Foramen Ovale Depth Electrodes, Marco-Micro Depth Electrodes, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrodes)
Applicant:	Ad-Tech Medical Instrument Corporation
Device Classification Name:	Electrode, Depth
Regulation Number:	21 CFR 882.1330
Common Name:	Depth Electrode
Device Class:	Class II
Classification Product Code:	GZL
Regulation Medical Specialty:	Neurology
510(k) Review Panel:	Neurology

g. Device Description

The Depth Electrodes (Spencer Probe Depth Electrode) are intended for recording, monitoring and stimulation at sub-surface levels of the brain. These electrodes are provided sterile, disposable and single patient use.

The Depth Electrodes (Spencer Probe Depth Electrodes) provide the patient contact device. The Depth Electrodes (Spencer Probe Depth Electrodes) connect to an electrode cable that is applied to the user's equipment. The electrodes are used by physicians. Physicians in the areas of biopotential recording, monitoring and stimulation/response studies understand the use of Depth Electrodes.

h. Intended Use / Indications for Use

The AD-TECH Depth Electrodes (Spencer Probe Depth Electrodes) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

i. Statement of Substantial Equivalence

Table 1 and Table 2 below presents a comparison of the Depth Electrodes (Spencer Probe Depth Electrodes) to the Predicate Depth Electrodes (K163355). Table 3 is a comparison of the optional accessory Stay Flange to the Predicate.

j. Comparison Tables

Table 1: Comparison Depth Electrodes

Feature	Depth Electrodes (Spencer Probe Depth Electrodes) (Under Review)	Depth Electrodes (Predicate K163355)	Comment
Indications for Use	The Ad-Tech Depth Electrodes (Spencer Probe Depth Electrodes) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The Ad-Tech Depth Electrodes (Depth Electrodes, Foramen Ovale Depth Electrodes, Macro Micro Depth Electrodes, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrodes) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	Same – The Indications for Use of the devices are the same. The only difference is that instead of listing the whole family of devices in the Predicate the device in this submission is limited to the Spencer Probe Depth Electrodes.
Clinical Application	Placed in the subsurface level of the brain to support recording, monitoring and stimulation.	Placed in the subsurface level of the brain to support recording, monitoring and stimulation.	Same
Contraindications	These depth electrodes should not be used on any patient who the physician/surgeon considers at risk for infection or for whom the surgical recording and stimulation procedure cannot be performed safely and effectively.	These depth electrodes should not be used on any patient who the physician/surgeon considers at risk for infection or for whom the surgical recording and stimulation procedure cannot be performed safely and effectively.	Same
Single patient use, Disposable	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Environment of Use	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations	Same
Duration of Use	< 30 days	< 30 days	Same
Electrode Contact Material	Platinum/Iridium	Platinum/Iridium	Same
Maximum Stimulation Charge Density	$\leq$ 30 $\mu C/cm^2$	$\leq$ 30 $\mu C/cm^2$	Same

The following table identifies features in comparison to the predicate device specific to the Spencer Probe Depth Electrodes.

Table 2: Comparison Depth Electrodes (Spencer Probe Depth Electrode)

Feature	Spencer Probe Depth Electrodes Under Review	Spencer Probe Depth Electrodes (Predicate K163355)	Comment
Number of electrode contacts	Up to 16	Up to 16	Same
Electrode Material	Platinum	Platinum	Same
Electrode body diameter (brain contact)	0.86 mm to 1.96 mm	0.86 mm to 1.96 mm	Same

Feature	Spencer Probe Depth Electrodes Under Review	Spencer Probe Depth Electrodes (Predicate K163355)	Comment
Stylet	Yes	Yes	Same
Neuro Navigation Stylet compatible	Yes (AD Style Only)	Yes (AD Style Only)	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 Depth Electrodes (Spencer Probe Depth Electrode) labeling has been updated with MR Conditional use information.			

Table 3: Comparison Optional Accessory Stay Flange

Feature	Stay Flange Under Review	Stay Flange (Predicate K163355)	Equivalence Comments
Indications for Use	The AD-TECH Depth Electrodes (Depth Electrode, Foramen Ovale Depth Electrode, Macro Micro Depth Electrode, Spencer Probe Depth Electrode, Wyler Sphenoidal Depth Electrode) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The AD-TECH Depth Electrodes (Depth Electrode, Foramen Ovale Depth Electrode, Macro Micro Depth Electrode, Spencer Probe Depth Electrode, Wyler Sphenoidal Depth Electrode) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	Same
Duration of use	< 30 days	< 30 days	Same
Single patient use, disposable	Yes	Yes	Same
Provided sterile	Yes	Yes	Same
Stay Flange	Yes Optional accessory placed around the Depth Electrode Tail that exists the skull, providing a surface to suture to the skin, preventing movement of the electrode.	Yes Optional accessory placed around the Depth Electrode Tail that exists the skull, providing a surface to suture to the skin, preventing movement of the electrode.	Same
Stay Flange patient contact material	Silicone	Silicone	Same
Compatible Depth Electrode Tail Diameter	0.86 mm to 1.3 mm	0.86 mm to 1.3 mm	Same

k. Performance Data

Ad-Tech, in conjunction with University of Houston, has conducted performance evaluations of the Depth Electrodes (Spencer Probe Depth Electrode) and optional accessory Stay Flange 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 4: 1.5T Test Results 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 5: 3.0T Test Results 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

Accessory Stay Flange Conductivity Testing

The optional accessory Stay Flange was tested for conductivity. The impedance was measured between two sample edges in air and in saline solution with conductivity of 0.47 S/m. In addition, impedance was measured between the two electrodes of multi-meter in saline without the sample.

Results showed that conductivity was negligible and use of the optional accessory Stay Flange would not lead to any additional safety concerns in association with MRI.

l. Conclusion

The Depth Electrodes (Spencer Probe Depth Electrodes) and optional accessory Stay Flange meet performance requirements. The intended use and technology of the Depth Electrodes (Spencer Probe Depth Electrodes) are the same as the predicate device.