DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 12, 2017

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

Re: K163355
Trade/Device Name: Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Marco Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode)
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: November 28, 2016
Received: November 30, 2016

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 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 yours,

Carlos L. Pena -S FDA

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163355

Device Name
Depth Electrodes (Depth Electrode, Foramen Ovale Depth Electrode, Macro Micro Depth Electrode, Spencer Probe Depth Electrode, Wyler Sphenoidal Depth Electrode)

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

AD-TECH® MEDICAL INSTRUMENT CORPORATION

5.0 510(k) Summary

This summary is provided to support the 510(k) pre-market notification for the Depth Electrodes.

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:	January 5, 2017
Trade Name:	Depth Electrodes (Depth Electrode, Foramen Ovale Depth Electrode, Macro Micro Depth Electrode, Spencer Probe Depth Electrode, Wyler Sphenoidal Depth Electrode)
Common Name:	Depth Electrode
Classification Name:	Depth Electrode 21 CFR 882.1330 Product Code: GZL Class II
Predicate Devices:	K053358 Depth Electrode (Primary Predicate) Ad-Tech Medical Instrument Corporation K964644 Depth Electrode Ad-Tech Medical Instrument Corporation K990788 Foramen Ovale Electrode Ad-Tech Medical Instrument Corporation K041604 Macro-Micro Depth Electrode Ad-Tech Medical Instrument Corporation K802151 and K151790 PMT Depthalon Electrodes PMT Corporation
Reference Device:	K944061 Cueva Cranial Nerve Electrode Ad-Tech Medical Instrument, Corporation

5.1 Product Description

The device under review is a family of Depth Electrodes. These electrodes provide sub-surface brain contact to support recording, monitoring and stimulation from user supplied equipment.

5.2 Intended Use of the Device

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.

The intended use of the Ad-Tech Depth Electrodes is not modified by this 510(k).

5.3 Summary of Technological Characteristics

The fundamental technical characteristics of the Depth Electrodes are not affected by this submission. Fundamentally the Depth Electrodes are a conductor of the biopotential signals from subsurface levels of the brain to the user's equipment and as applicable conductors of the stimulation energy from the user's equipment to subsurface levels of the brain.

The following table provides a side-by-side comparison of the Depth Electrodes to the predicate devices applied to support this pre-market notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	Depth Electrodes (Under Review)	Depth Electrodes (Primary Predicate K053358)	Comment
Indications for Use	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.	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
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	Intraoperative and Neurological	Intraoperative and Neurological	Same

Table 5.3-1: Substantial Equivalence Technical Characteristics			
Feature	**Depth Electrodes (Under Review)**	**Depth Electrodes (Primary Predicate K053358)**	**Comment**
Use	monitoring locations	monitoring locations	
Duration of Use	< 30 days	< 30 days	Same
Electrode Contact Material	Platinum/Iridium	Platinum/Iridium	Same
Maximum Stimulation Charge Density	$\leq$ 30 µC/cm^2	Not indicated in labeling	Clarification of stimulation charge density limits for brain tissue.

The following table identifies features in comparison to predicate by Depth Electrode Commercial Name.

Table 5.3-2: Feature comparison Spencer Probe Depth Electrodes				
Feature	**Depth Electrodes Under Review**	**Depth Electrode (Predicate K053358 and K964644)**	**PMT Depthalon Electrodes (Predicate K802151, K151790)**	**Equivalence Comments**
Number of electrode contacts	Up to 16	Up to 12	Up to 16 contacts	Equivalent
Electrode Material	Platinum	Platinum	Platinum or Stainless Steel	Same
Electrode body diameter (brain contact)	0.86 mm to 1.96 mm	1 mm	0.8 mm to 1.8 mm	Equivalent Variations of electrode body diameter are provided.
Stylet	Yes	Yes	Yes	Same
Neuro Navigation Stylet compatible	Yes (AD Style Only)	No	Yes (ACCUNAC® variation)	Equivalent

Table 5.3-3: Foramen Ovale Depth Electrodes Feature Comparison			
Feature	**Foramen Ovale Depth Electrodes Under Review**	**Foramen Ovale Electrode (Predicate K990788)**	**Equivalence Comments**
Number of electrode contacts	Up to 6	Up to 6	Same
Electrode Material	Platinum	Platinum	Same
Electrode body diameter (brain contact)	1.1 mm	1.0 $\pm$ 0.5 mm	Equivalent Within the tolerance of the predicate.
Overall length	$\leq$ 660 mm	$\leq$ 383 mm	A longer electrode accommodates additional contacts and user preference.

Table 5.3-4: Feature Comparison of Macro Micro Depth Electrodes			
Feature	**Macro Micro Depth Electrodes Under Review**	**Macro-Micro Depth Electrode (Predicate K041604)**	**Equivalence Comments**
Number of electrode contacts	Up to 12 (Macro) Up to 24 (Micro) (Up to 32 total contacts)	Up to 12 (Macro) Up to 10 (Micro)	Additional Micro Electrode contacts are available.
Electrode Material	Platinum (Macro Electrode) Platinum/Iridium (Micro Electrode)	Platinum (Macro Electrode) Platinum/Iridium (Micro Electrode)	Same
Electrode body diameter (brain contact)	1.3 mm (Macro) 38 to 51 microns (Micro)	1.2 to 1.4 mm (Macro) 15 to 30 microns (Micro)	Equivalent
Electrode contact length (along body of the electrode)	1.57 mm (Macro)	1.32 to 1.57 mm (Macro)	Same
Overall length	≤ 660 mm	≤ 400 mm	A longer electrode accommodates user preference.
Stylet	Yes	Yes	Same

Table 5.3-5: Stay Flange Comparison to Reference Device			
Feature	**Depth Electrodes Under Review**	**Cueva Cranial Nerve Electrode (Reference Device K944061)**	**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 Cueva Cranial Nerve Electrode is intended for use to monitor cranial nerves during skull base type surgeries. It is not for implantation and is to be used for surgical procedures only. The electrode and applicator are for single use only, not for reuse. The electrode and applicator are not to be resterilized.	Equivalent monitoring indication of intracranial nerves. The Cueva Electrode resides on the surface of a nerve. The Depth Electrodes are placed subsurface of a nerve (brain).
Duration of use	< 30 days	≤ 10 hours	The Cueva Electrode reference device is limited to intraoperative use.
Single patient use,	Yes	Yes	Same

Table 5.3-5: Stay Flange Comparison to Reference Device			
Feature	**Depth Electrodes Under Review**	**Cueva Cranial Nerve Electrode (Reference Device K944061)**	**Equivalence Comments**
disposable			
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 Molded onto electrode Tail. Suture of Stay flange for securing of connector end electrode, prevents movement of electrode.	Equivalent For both devices the Stay Flange provides a suturing surface to support stabilizing the electrode tail.
Stay Flange patient contact material	Silicone	Silicone	Equivalent
Compatible Depth Electrode Tail Diameter	0.86 mm to 1.3 mm	Not Applicable Molded onto Electrode Tail.	The Stay Flange is an optional accessory to variations of Depth Electrodes. The Stay Flange is placed around the Depth Electrode tail and provides an optional method of providing Depth Electrode retention and a surface for suturing the Stay Flange to skin.

5.4 Performance Tests to Demonstrate Substantial Equivalency

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

Test	Summary of Requirement	Result
Electrical Resistance	Measure electrical resistance from the electrode contact to connector.	Pass
Dimensional Characteristics	Dimensional requirements are met by manufacturing.	Pass
Stimulation affect	Stimulation at 30 $\mu C/cm^2$ does not affect the electrodes.	Pass
Optional Accessory Stay Flange	The optional accessory Stay Flange supports adequate Depth Electrode retention.	Pass

5.5 Conclusion

The Depth Electrodes meet performance requirements. The intended use and technology of the Depth Electrodes are the same as the predicate devices.