DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 4, 2016

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

Re: K152547
Trade/Device Name: DNAP Electrode
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL, GYC
Dated: September 2, 2015
Received: September 8, 2015

Dear Gary 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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.03.04 20:58:21 -05'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152547

Device Name
DNAP Cranial Nerve Electrodes

Indications for Use *(Describe)*
The DNAP Cranial Nerve Electrodes are designed for intraoperative monitoring/recording for less than or equal to 10 hours from the cochlear cranial nerves during skull based surgical procedures when connected to the MEE-1000A or MEE-2000 Neural Function Measuring System.

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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AD-TECH® MEDICAL INSTRUMENT CORPORATION

5.0 510(k) Summary

This summary is provided to support the 510(k) premarket notification for the DNAP Cranial Nerve Electrode.

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 21, 2016
Trade Name:	DNAP Cranial Nerve Electrode
Common Name:	Cortical Electrode
Classification Name:	Depth Electrode 21 CFR 882.1330 Product Code: GZL, GYC Class II
Predicate Devices:	K944061 Cueva Cranial Nerve Electrode Ad-Tech Medical Instrument Corporation

5.1 Product Description

The DNAP Cranial Nerve Electrode (DNAP electrode) is intended for intraoperative nerve monitoring/recording during acoustic neuroma surgery or tumor removal (such as meningioma) at the CP-angle during surgical procedures. The DNAP electrodes are non-active and are intended to be connected to Nihon Kohden Corporation's Neural Function Measuring System MEE-1000A or MEE-2000 Neural Function Measuring System.

The DNAP electrode is a single patient use, disposable cranial nerve electrode used for recording cranial nerve action potentials. The DNAP electrode may be used for recording the action potentials of cochlear nucleus elicited by auditory stimulation. The user places the electrode on the dorsal cochlear nuclei. Access to the dorsal cochlear nuclei may be through the foremen of Luschka. This potential is called DNAP (dorsal cochlear nucleus action potential), and used to preserve cochlear nerve function especially during acoustic neuroma surgery or tumor removal (such as meningioma) at the CP-angle.

5.1 Intended Use of the Device

The intended use of the DNAP electrode is the same as the predicate device: The DNAP Cranial Nerve Electrodes are designed for intraoperative monitoring/recording for less than or equal to 10 hours from the cochlear cranial nerve during skull based surgical procedures when connected to the MEE-1000A or MEE- 2000 Neural Function Measuring System.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison the DNAP electrode to the predicate devices applied to support this notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	DNAP Electrode (Under Review)	Cueva Electrode (Predicate K944061)	Comment
Indications for Use	The DNAP Cranial Nerve Electrodes are designed for intraoperative monitoring/recording for less than or equal to 10 hours from the cochlear cranial nerve during skull based surgical procedures when connected to the MEE-1000A or MEE-2000 Neural Function Measuring System.	The Cueva Cranial Nerve Electrode is intended for use to monitor cranial nerves during skull base type surgeries.	The indication for use of the DNAP electrode is the same as the predicate device with regard to intraoperative monitoring (recording) from the surface of cranial nerves. The DNAP Electrode is applied to the surface of the Cochlear Nerve, which is an application of the Cueva Electrode.
Clinical Application	The DNAP electrode records cranial nerve action potentials. The DNAP electrode may be used for recording the action potentials of cochlear nucleus elicited by auditory stimulation.	Cueva Cranial Nerve electrodes provide direct cranial nerve monitoring during skull based surgeries.	Both electrodes are applied to the surface of nerves to monitor within the skull during intraoperative procedures.
Contraindications	The DNAP cranial nerve electrodes should not be used on any patient who the physician/surgeon considers at risk for infection or for whom the surgical recording procedure cannot be performed safely and effectively. This device is not intended for use in MRI procedures.	The Cueva Electrode should not be used on any patient who the physician/surgeon considers at risk for infection.	Same
Magnetic Resonance Imaging (MRI) Compatibility	No	No	Same
Single patient use, Disposable	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	DNAP Electrode (Under Review)	Cueva Electrode (Predicate K944061)	Comment
Duration of Use	≤ 10 hours	≤ 10 hours	Same intraoperative
Environment of Use	Intraoperative	Intraoperative	Same intraoperative use
Electrode Material	Platinum/Iridium	Platinum/Iridium	Same material
Number of Electrode Contacts	One (1)	One (1)	Same

5.4 Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the DNAP electrode, 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
DNAP electrode Connector compatibility with monitor equipment.	Verify the DNAP electrode Connector is able to connect to neural function measuring systems.	Pass
Electrical continuity and resistance after tensile testing.	Verify electrical continuity and resistance properties are met after tensile load applied to the DNAP electrode.	Pass
Electrode separation under tensile test.	No electrode head separation with a load under tensile test.	Pass
Electrical continuity and resistance after simulated use.	Apply a simulated monitoring potential for the ≤ 10 hour anticipated duration of intraoperative use.	Pass
Overall length.	Confirm dimensional requirements are met.	Pass

Biocompatibility evaluations of manufactured and sterilized DNAP Electrodes were performed for Cytotoxicity, Sensitization, Intracutaneous and Acute Systemic Toxicity.

5.5 Conclusion

The DNAP electrode meets performance requirements. The intended use and technology of the DNAP electrode are equivalent to the predicate device.