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

May 6, 2016

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

Re: K152769
Trade/Device Name: FREMAP Electrode
Regulation Number: 21 CFR 882.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN, GZL, GYC
Dated: April 7, 2016
Received: April 8, 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,

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: 2016.05.06 08:44:04 -04'00'

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)*
K152769

Device Name

FREMAP Cranial nerve Electrode

Indications for Use *(Describe)*

The FREMAP Cranial Nerve Electrodes are designed for intraoperative (=< 10 hours) monitoring/recording from and stimulation to the facial nerve or facial nerve root at the CP angle 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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5.0 510(k) Summary

This summary is provided to support the 510(k) pre-market notification for the FREMAP 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:	May 5, 2016
Trade Name:	FREMAP Cranial Nerve Electrode
Common Name:	Cortical Electrode
Classification Name(s): (Predicates and Reference Devices)	21 CFR 874.1820 Surgical Nerve Stimulator/Locator Product Code: ETN Class II 21 CFR 882.1330 Depth Electrode Product Code: GZL Class II 21 CFR 882.1310 Cortical Electrode Product Code: GYC Class II
Predicate Devices:	K133348 IOM Stimulator Probes (Primary Predicate) K944061 Cueva Cranial Nerve Electrode
Reference Device:	K053363 Subdural Electrode

5.1 Product Description

The device under review is a Facial nerve Root Evoked Muscle Action Potential (FREMAP) electrode. The electrode is used to elicit the muscle action potentials by electric stimulation directly to the facial nerve. It is commonly placed on the facial nerve or facial nerve root at the CP-angle and is used for monitoring (elicit) the muscle action potential response to preserve the facial nerve function especially during acoustic neuroma surgery or tumor removal (such as meningioma) at the CP-angle.

The FREMAP electrodes are non-active and are intended to be connected to Nihon Kohden Corporation's Neural Function Measuring System Neuromaster MEE-1000A or MEE-2000

5.2 Intended Use of the Device

The intended use of the FREMAP electrode is the same as predicate devices:

> The FREMAP Cranial Nerve Electrodes are designed for intraoperative (≤ 10 hours) monitoring/recording from and stimulation to the facial nerve or facial nerve root at the CP angle 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 FREMAP electrode to the predicate devices applied to support this pre-market notification.

Feature	**FREMAP Electrode (Under Review)**	**Cueva Electrode (Predicate K944061)**	**IOM Stimulator Probes (Primary Predicate K133348)**	***FREMAP Electrode Equivalence Discussion***
Intended Use	The FREMAP cranial nerve electrodes are intended for nerve monitoring/recording and stimulation during acoustic neuroma surgery or tumor removal at the CP-angle.	The Cueva Cranial Nerve Electrode is intended for use to monitor cranial nerves during skull base type surgeries.	IOM Stimulator Probes are used by the surgeon as the medium to deliver electrical stimulation to tissue during intra-operative neurological monitoring, to identify nerves and spinal nerve roots and to assess nerve function. IOM Stimulator Probes disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral nerves for location and identification during surgery, including spinal nerve roots.	The FREMAP cranial nerve electrodes combine the intended use of monitoring cranial nerves and a nerve contacting stimulation electrode (probe) for cranial nerves (facial nerve and facial nerve root).
Indications for Use	The FREMAP Cranial Nerve Electrodes are designed for intraoperative (≤ 10 hours) monitoring/recording from the facial nerve or facial nerve root at the CP angle during skull based surgical procedures when connected to the MEE-1000A or MEE-2000 Neural Function Measuring System.	The 510(k) submission references use on the Cochlear cranial nerve, Facial nerve, Glossopharyngeal nerve, Hypoglossal nerve, Spinal accessory nerve and Vagus nerve.		The indication for use of the FREMAP electrode is the same as the predicate devices with regard to intraoperative use for monitoring (recording) from the surface of cranial nerves (the facial nerve is one of the predicate Cueva nerves monitored) and application of stimulation for an evoked response of the facial nerve and facial nerve root (the IOM Neural Stimulator Probe Insulated Monopolar is applied

Feature	FREMAP Electrode (Under Review)	Cueva Electrode (Predicate K944061)	IOM Stimulator Probes (Primary Predicate K133348)	*FREMAP Electrode Equivalence Discussion*
				for stimulation of cranial nerves.) The facial nerve and facial nerve root are cranial nerves.
Contraindications	The FREMAP 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 and stimulation 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.	Unknown	Same with regard to the risk for infection from the predicate Cueva Electrode.
Clinical Use	The FREMAP electrode records cranial (facial nerve and facial nerve root) action potentials and may be used for stimulation of these nerves.	Cueva Cranial Nerve electrodes provide direct cranial nerve monitoring during skull based surgeries.	IOM Stimulator Probes provide direct cranial nerve stimulation (monitoring) during intraoperative skull based surgeries.	All electrodes (probes) are applied to the surface of the nerve to support nerve recording and stimulation within the skull during intraoperative procedures.
Fundamental Technical Function	Monopolar electrode contact placed on the surface of the nerve by the user, in support of monitoring and stimulating the nerve.	Monopolar electrode contact placed on the surface of the nerve by the user, in support of monitoring nerve function.	Monopolar electrode contact placed on the surface of the nerve by the user, in support of stimulation of the nerve.	The fundamental technical function of the FREMAP electrode and the predicate Cueva electrode, IOM Stimulator Probe is the same.
Single Patient Use, Disposable	Yes	Yes	Yes	Same
Provided Sterile	Yes	Yes	Yes	Same
Environment of Use	Intraoperative	Intraoperative	Intraoperative	Same intraoperative use
Duration of Use	$\leq$ 10 hours	$\leq$ 10 hours	Intraoperative (Assumed to be $\leq$ 10 hours)	Same intraoperative duration of use.
Number of Electrode Contacts	One (1)	One (1)	One (1)	Monopolar, one electrode contact.
Electrode Material	Platinum/Iridium	Platinum/Iridium	Stainless steel	Same as Cueva electrode for recording. A reference

Feature	FREMAP Electrode (Under Review)	Cueva Electrode (Predicate K944061)	IOM Stimulator Probes (Primary Predicate K133348)	*FREMAP Electrode Equivalence Discussion*
				device with Platinum/Iridium as the nerve stimulating electrode contact is discussed.

Features of the FREMAP electrode compared to the Predicate and Reference device are addressed below.

FREMAP Electrode Discussion				
Feature	**FREMAP Electrode (Under Review)**	**Cueva Electrode (Predicate K944061)** **IOM Stimulator Probes (Primary Predicate K133348)**	**Subdural Electrode (Reference Device K05336)**	***Safety and Effectiveness Discussion***
Fundamental Technical Function	The FREMAP Electrode has a monopolar electrode disk contact. The monopolar electrode contact is placed on the surface of the nerve by the user, in support of recording from and stimulating to the nerve.	The Cueva electrode has a monopolar electrode contact on a C-shaped radius. The IOM stimulator probe (Neural Stimulator Probe Insulated Monopolar) electrode has a monopolar electrode contact as a sphere. For both predicates, the monopolar electrode contact is placed on the surface of the nerve by the user, in support of recording from and stimulating to the nerve.	The reference subdural electrodes are a circular disc. The electrode contacts are placed on the surface of the nerve (brain) by the user, in support of recording from and stimulation to the nerve.	The FREMAP electrode is equivalent to the circular disk of the reference Subdural Electrode. The Subdural electrodes are indicated for recording from and stimulation to a cranial nerve, the brain.
Electrode Material	Platinum/Iridium	Cueva: Platinum/Iridium (Recording) IOM Probe: Stainless Steel (Stimulation)	Platinum/Iridium (Recording and Stimulation) or Stainless Steel (Recording and Stimulation)	The reference Subdural electrode applies the same Platinum/Iridium as the stimulating electrode contact material to nerve tissue.

5.4 Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the FREMAP electrode, evaluations were conducted to evaluate compliance with performance requirements, including:

Test	Summary of Requirement
Electrical Resistance	Measure electrical resistance from the electrode contact to connector.
FREMAP electrode Connector compatibility with monitor	Verify the FREMAP electrode Connector is able to connect to neural function measuring systems.

Test	Summary of Requirement
equipment	
Electrical continuity and resistance after tensile testing	Verify electrical continuity and resistance properties are met after tensile load was applied to the FREMAP electrode.
Electrode separation under tensile test	Evaluate risk of electrode head separation with a load under tensile test.
Electrical continuity and resistance after simulated use.	Apply a simulated stimulation potential for the 10 hour anticipated duration of intraoperative use.
Overall length	Confirm dimensional requirements are met.

Test requirements were met or a process monitor is in place to confirm compliance.

Biocompatibility evaluations of manufactured and sterilized FREMAP Electrodes were performed for Cytotoxicity, Sensitization, Intracutaneous Test and Acute System Toxicity.

5.5 Conclusion

The FREMAP electrode meets performance requirements. The intended use and technology of the FREMAP electrode are the same as the predicate devices.