March 8, 2021

iCE Neurosystems, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue
Suite B-257
San Diego, California 92110

Re: K201678
Trade/Device Name: iCE-SG Subcutaneous Electrode Arrays
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: March 3, 2021
Received: March 4, 2021

Dear Allison Komiyama:

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,

Jay Gupta
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)*
K201678

Device Name
iCE-SG Subcutaneous Electrode Arrays

Indications for Use *(Describe)*
iCE-SG Subcutaneous Electrode Arrays are intended for temporary (<14 days) use with recording and monitoring equipment for the recording and monitoring of electrical signals at the subsurface level of the brain.

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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510(k) Summary

K201678

DATE PREPARED

March 8, 2021

MANUFACTURER AND 510(k) OWNER

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DEVICE INFORMATION

Proprietary Name/Trade Name: iCE-SG Subcutaneous Electrode Arrays

Common Name:	Depth electrode
Regulation Number:	21 CFR 882.1330
Class:	Class II
Product Code:	GZL
Review Panel:	Neurology
Premarket Review:	Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)

PREDICATE DEVICE IDENTIFICATION

The iCE-SG Subcutaneous Electrode Arrays is substantially equivalent to the following predicate and reference devices:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K163355	Depth Electrodes (Depth Electrode, Foramen Ovale Depth Electrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) / Ad-tech Medical Instrument Corporation	✓
K961942	Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring / Radionics Inc.	

DEVICE DESCRIPTION

The iCE-SG Subcutaneous Electrode Arrays are intended for use with recording and monitoring equipment for the purpose of recording electroencephalograph (EEG) signals. The subject device allows for continuous EEG monitoring in the subcutaneous space. The iCE-SG Subcutaneous Electrode Arrays can connect to commonly used electrophysiology systems. The subject device is provided sterile and for single patient use in hospitals by healthcare professionals (HCPs).

A kit includes the following components:

1. Preparation box
2. Insertion kit box
3. Two iCE-SG electrode boxes

INDICATIONS FOR USE

iCE-SG Subcutaneous Electrode Arrays are intended for temporary (<14 days) use with recording and monitoring equipment for the recording and monitoring of electrical signals at the subsurface level of the brain.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

iCE Neurosystems believes that the iCE-SG Subcutaneous Electrode Arrays are substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use and similar technological characteristics as the devices cleared in K163355 and K961642. The electrode array used in the subject device is the same as the electrode array cleared in K163355. The insertion methodology is the same or similar to K163355 and K961942. Overall, the iCE-SG Subcutaneous Electrode Arrays have undergone testing to ensure that any difference in technological characteristics (i.e., inclusion of a preparation and insertion kit) do not affect safety and effectiveness when compared to the predicate device. A SE chart is included at the end of this summary.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the iCE SG-Subcutaneous Electrode Arrays. The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility: Patient contacting material was subjected to biocompatibility testing in compliance to ISO 10993-1 *Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process*.

Standard	Study Description	Results
Insertion kit		
ISO 10993-5	Cytotoxicity study using L-929 cells; EMEM extract; Evaluated using percent viability.	Non-cytotoxic
ISO 10993-10	Intradermal injection and topical application in guinea pigs; sesame oil or 0.9% normal saline extracts.	Non-sensitizing
ISO 10993-10	Intracutaneous injection in New Zealand white rabbits; cottonseed oil or sodium chloride extracts.	Non-irritating
ISO 10933-11	Intraperitoneal injection of albino swiss mice with cottonseed oil or sodium chloride extracts.	Non-toxic
ISO 10993-11	Marginal ear vein injection of New Zealand white rabbits; 0.9% sodium chloride extract.	Non-pyrogenic
iCE-SG Electrode Arrays		
ISO 10993-5	Cytotoxicity study using L-929 cells; EMEM extract; Evaluated using morphological grading.	Non-cytotoxic
ISO 10993-10	Intradermal injection and topical application in guinea pigs; cottonseed oil or 0.9% sodium chloride extracts	Non-sensitizing

Standard	Study Description	Results
ISO 10993-10	Intracutaneous injections in New Zealand white strain albino rabbits; cottonseed oil or 0.9% sodium chloride extracts.	Non-irritating
ISO 10993-11	Intraperitoneal injection in albino swiss mice with cottonseed oil extract Intravenous injection in albino swiss mice with 0.9% sodium chloride extract	Non-toxic
ISO 10993-11	Marginal ear vein injection of New Zealand white albino rabbits; 0.9% sodium chloride extract.	Non-pyrogenic
ISO 10993-6 ISO 10993-11	Implantation of two articles maintained for 28 and 29-days (males or females, respectively).	Non-toxic
ISO 10993-6	Implantation for four weeks into the left hemisphere in New Zealand White rabbits.	Non-bioreactive
ISO 10993-3	Genotoxicity study with L5178Y cells; RPMIi and polyethylene glycol 400 (PEG) extracts; Visual assessment of colonies.	Non-mutagenic
ISO 10993-3	Top agar plating metabolically activated and incubated for 48 - 72 hours; physiological saline and polyethylene glycol 400 (PEG) extracts	Non-mutagenic

The following tests were performed to demonstrate equivalence to the predicate device:

- Performance Testing (Bench)
    - Examination of kit component dimensions
    - Examination of the packaging opening orientation
    - Examination of kit components colors, markings, and graphics
    - Examination for sharp edges
    - Examination of the opacity of the packaging
    - Examination of the trocar sheath tool's penetration tip bending force endurance
    - Examination of the bending force endurance of the exit assist device
    - Examination of the holding endurance of the posterior stopper
    - Examination of the trocar sheath tool adhesion endurance
    - Examination of the adhesion of the passage assist device
    - Examination of the passage assist device bending resistance
    - Examination of the anterior stopper endurance
    - Cadaver study
- Performance Testing (Animal)
    - Durability of the subject device to record EEG after 14 days continuous implantation in the subcutaneous space

The results of these tests indicate that the iCE-SG Subcutaneous Electrode Arrays are substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, biocompatibility and performance testing (bench and animal), it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed iCE-SG Subcutaneous Electrode Arrays are assessed to be substantially equivalent to the predicate device.

	Subject Device	*Primary Predicate Device*	*Secondary Predicate Device*	*Statement of Equivalence*
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Indications for Use	iCE-SG Subcutaneous Electrode Arrays are intended for temporary (<14 days) use with recording and monitoring equipment for the recording and monitoring of electrical signals at the subsurface level of the brain.	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.	Radionics Epidural Peg, Sphenoidal and Foramen Ovale Depth Electrodes are indicated for intraoperative recording of electrical signals for epilepsy monitoring at the surface and subsurface levels of the brain.	Substantially equivalent to the primary predicate device. The subject device is intended for use up to 14 days, is only for recording/monitoring, and the indications do not mention epileptogenic foci and brain mapping. This does not raise new questions of safety and effectiveness.
Product Codes / Regulation Number	GZL / 21 CFR 882.1330	GZL / 21 CFR 882.1330	GZL / 21 CFR 882.1330 GYC / 21 CFR 882.1310	Identical to the primary and secondary predicate devices.
Regulation Description	Depth electrode	Depth electrode	Depth electrode Cortical electrode	Identical to the primary and secondary predicate devices.

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***	***Statement of Equivalence***
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Use Environment	Hospitals including ICU	Intraoperative and neurological monitoring locations within a hospital setting	Unknown	Substantially equivalent to the predicate device. The subject device can be used in the same and similar environments as well as by the bedside due to the convenience kits included in the subject device. This does not raise new questions of safety and effectiveness.
Device Components	• Surgical Ruler • Marker pen • Sterile drape • Gauze pad • Head drape • Trocar sheath tool • Passage assist tool • Exist assist device • Stoppers • Body adhesive • iCE-SG Electrode Array	• Depth electrode array	• Depth electrode arrays	Substantially equivalent to the primary and secondary predicate devices. The subject device is provided with two convenience kits (Preparation Kit and Insertion Kit) to make subject use easier for the user. The nonclinical testing has demonstrated that these kits do not raise new questions of safety and effectiveness.

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***	***Statement of Equivalence***
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Insertion Kit Components	• Gauze pad • Head drape • Trocar sheath tool • Passage assist tool • Exist assist device • Stoppers • Body adhesive	(n/a)	(n/a)	The primary and secondary predicate devices are tunneled through the subcutaneous space and out of the skin using a trocar that is not included with the cleared devices. The trocars are sold separately by the manufacturers. These differences raise no new questions of safety or effectiveness.
Location of Placement	Extracranially	Extracranially	Extracranially	Identical to the primary and secondary predicate.
Duration of Use	<14 days	<30	Unknown	Substantially equivalent to the primary predicate device. The subject device is intended to be used for a shorter period of time compared to the primary predicate. Based on the results of the nonclinical data, the shorter time period does not raise new questions of safety and effectiveness.

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***	***Statement of Equivalence***
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Contraindications	These depth electrodes should not be used on any patient who the physician considers at risk for infection or for whom the insertion 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.	Unknown	Substantially equivalent to the primary predicate. The subject device does not stimulate. Based on the results of the nonclinical data, there are no new questions of safety and effectiveness.
	Technological Characteristics			
Electrode configuration	Array	Array	Array	Identical to the primary and secondary predicate devices. There are no new questions of safety and effectiveness.
Single Patient Use	Yes	Yes	Yes	Identical to the primary predicate device. There are no new questions of safety and effectiveness.
Disposable	Yes	Yes	Yes	Identical to the primary predicate device. There are no new questions of safety and effectiveness.
Electrode Material	Platinum Iridium	Platinum Iridium	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***	***Statement of Equivalence***
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Electrode Diameter	1.12 mm	0.86 – 1.96 mm	Unknown	Identical to the primary predicate. The diameter of the subject device falls within the cleared range for the primary predicate device, therefore there are no new questions of safety or effectiveness raised.
Maximum Stimulation Charge Density	< 30 µC/cm^2	< 30 µC/cm^2	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness. This technological characteristic is not applicable for the iCE-SG Subcutaneous Electrode Arrays as the iCE-SG Electrode Arrays are not used for stimulation.

Insertion Procedure	• The marked entry/exit sites are prepped in a sterile fashion. • The iCE-SG Electrode Array and trocar insertion tool are inserted and tunneled subcutaneously into the exit point of the skin. • One placed, the trocar sheath tool is brought out through the skin with help from the exist assist device. The trocar sheath tool is then removed from the subcutaneous pace, leaving the electrode in place in the subcutaneous space. The electrode is secured in position with two stopper devices. • A period of monitoring (up to 14 days) occurs. Following completion of monitoring, the iCE-SG Subcutaneous Electrode Array is withdrawn at the bedside.	• The entry/exit sites are prepped and draped in sterile fashion. • The Depth Electrode and trocar insertion tool are inserted and tunneled subcutaneously to the exit point of the skin. • The trocar is brought out through the skin and then removed from the subcutaneous space, leaving the electrode in place in the subcutaneous space. The electrode is secured in position using a stay flange. • A period of monitoring (up to 30 days) occurs. Following completion of monitoring, the Depth Electrode is withdrawn at the bedside.	Unknown	Substantially equivalent to the primary predicate. The subject device is inserted for 14 days, less time than the primary predicate. This does not raise new question of safety and effectiveness.
Use of Stylet	Stylet removed prior to passage of electrode into sheath and subcutaneous space.	Stylet removed prior to passage into trocar and subcutaneous space.	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness.

	Subject Device	***Primary Predicate Device***	***Secondary Predicate Device***	***Statement of Equivalence***
	iCE Neurosystems, Inc. / iCE-SG Subcutaneous Electrode Arrays K201678	Ad-Tech Medical Instrument Corporation / Depth Electrodes (Depth Electrode, Foramen Ovale Depth Eletrodes, Macro Micro Depth Electrode, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrode) K163355	Radionics, Inc. / Epidural Peg Electrode (EP), Sphenoidal Electrode (EDS) and Foramen Ovale Depth Electrode (ED-FO) for Epilepsy Monitoring K961942	
Impedance Cutoff for Each Electrode Contact Prior to Product Release (kΩ)	0.25	0.25	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness.
	Testing			
Biocompatibility	Per 10993-1	Per 10933-1	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness.
Performance Testing	• Visual tests • Functional tests • Cadaver study • Animal study	• Functional Tests	Unknown	Substantially equivalent to the primary predicate. There are no new questions of safety and effectiveness.
Sterilization	Ethylene oxide	Ethylene oxide	Unknown	Identical to the primary predicate device. There are no new questions of safety and effectiveness.