December 6, 2022

iCE Neurosystems, Inc.
% Allison Komiyama
Principal Consultant
RQM+
2251 San Diego Avenue
Suite B-257
San Diego, California 92110

Re: K222706
Trade/Device Name: iCE-SG2 Subcutaneous Electrode Kit
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: September 6, 2022
Received: September 7, 2022

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,

Patrick Antkowiak -S

for
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.

Submission Number *(if known)*

Device Name

iCE-SG2 Subcutaneous Electrode Kit

Indications for Use *(Describe)*

iCE-SG2 Subcutaneous Electrode Kit is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

DATE PREPARED
November 8, 2022

MANUFACTURER AND 510(k) OWNER
iCE Neurosystems, Inc.
1010 Wisconsin Avenue NW, Suite 307
Washington, DC 20007, USA
Telephone: (202) 918-3205
Official Contact: Emir Kapetanovic, Chief Operating Officer

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., RAC
Erin A. Gontang, Ph.D.
RQM+
Telephone: (412) 816-8253
Email: akomiyama@rqmplus.com; egontang@rqmplus.com
Website: https://www.rqmplus.com/

DEVICE INFORMATION

Proprietary Name/Trade Name:	iCE-SG2 Subcutaneous Electrode Kit
Common Name:	Electrode, Depth
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-SG2 Subcutaneous Electrode Kit is substantially equivalent to the following primary predicate device:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K201678	iCE-SG Subcutaneous Electrode Arrays / iCE Neurosystems, Inc.	✓

DEVICE DESCRIPTION
The iCE-SG2 Subcutaneous Electrode Kit is 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 subject device allows for continuous

electroencephalograph (EEG) monitoring in the subcutaneous space. The iCE-SG2 Subcutaneous Electrode Kit can connect to commonly used electrophysiology systems. The subject device is provided sterile and for single patient use in hospitals by healthcare professionals (HCPs).

The iCE-SG2 Subcutaneous Electrode Kit includes the following components:

Item	Quantity	Kit Component	510(k) Status
1	2	iCE-SG2 Subcutaneous Electrode	Pending Clearance
2	2	14-gauge Touhy needle with stylet	Pending Clearance
3	1	Surgical marking pen and ruler	510(k) Exempt
4	2	Skin disinfectant device	NDA020832
5	1	Sterile table drape	K140330
6	2	Sterile gauze pad	510(k) Exempt
7	2	Electrode securement dressing	510(k) Exempt
8	2	Cable securement dressing	510(k) Exempt

INDICATIONS FOR USE

iCE-SG2 Subcutaneous Electrode Kit is 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-SG2 Subcutaneous Electrode Kit is substantially equivalent to the primary predicate device based on the information summarized below.

The electrodes of the subject device have the identical intended use and similar technological characteristics as the device cleared in K201678. Both the subject device and primary predicate device include depth electrode arrays that are placed in the subcutaneous space to detect electrical signals at the subsurface level of the brain. The electrodes of both the subject device and the primary predicate device are intended for temporary use (<14 days) in hospitals, including intensive care units (ICUs). While the electrodes of the subject device have eight contacts, whereas the predicate device has ten, the decreased number of contacts (and thereby decreased recording length and overall depth length) does not affect the recording performance of the subject device.

The insertion methodology of the subject device is similar to K201678. Overall, the iCE-SG2 Subcutaneous Electrode Kit has undergone testing to ensure that any difference in technological characteristics (i.e., insertion procedure) do not affect safety and effectiveness when compared to the predicate device.

As detailed in the device description, components of the iCE-SG2 Subcutaneous Electrode Kit have either been determined to be substantially equivalent to the predicate device, 510(k) exempt, or previously cleared or approved by FDA. While the electrodes and insertion needles associated with the kit have been determined to be substantially equivalent as part of the current 510(k), the skin disinfectant device was previously approved and the sterile table drape previously cleared by FDA. The remaining kit components, including the surgical marking pen and ruler, sterile gauze pads, and securement dressings are all 510(k) exempt medical devices that are provided in their final finished form, consistent with their legal marketing authorization. An SE chart is included at the end of this summary.

SUMMARY OF NON-CLINICAL TESTING

The results of these tests indicate that the iCE-SG2 Subcutaneous Electrode Kit is substantially equivalent to the predicate device.

- *BIOCOMPATIBILITY*
  The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This evaluation of the device included relevant data sources related to biological safety of finished device testing of the previously cleared product (K201678) and kit components with history of safe biological use. This biocompatibility evaluation establishes the biological safety for the iCE-SG2 Subcutaneous Electrode Kit.

- *PERFORMANCE TESTING (BENCH)*
  A cadaver study was conducted using ten electrodes to demonstrate reproducibility in the following phases: insertion of the electrode array through the needle within the subcutaneous space, stability of the electrode array position, and removal of electrode arrays from the subcutaneous space. Pre-insertion and post-removal impedance testing of the electrodes was also performed. Based on the prespecified criteria, all 10 out of 10 electrode arrays performed successfully. Functions associated with electrode array insertion, stability, and removal were shown to perform as expected.

CONCLUSION

Based on the testing performed (i.e., biocompatibility and performance testing (bench)), it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The identical indications for use, similar technological characteristics, and similar performance characteristics for the proposed iCE-SG2 Subcutaneous Electrode Kit are assessed to be substantially equivalent to the predicate device.

510(k) Summary

	Subject Device	***Predicate Device***
	iCE Neurosystems, Inc. iCE-SG2 Subcutaneous Electrode Kit K222706	iCE Neurosystems, Inc. iCE-SG Subcutaneous Electrode Arrays K201678
Indications for Use	iCE-SG2 Subcutaneous Electrode Kit is 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.	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.
Product Codes / Regulation Number	GZL / 21 CFR 882.1330	GZL / 21 CFR 882.1330
Regulation Description	Depth electrode	Depth electrode
Use Environment	Hospitals including ICU	Hospitals including ICU
Device Components	• Surgical Ruler • Pen • Sterile Drape • Disinfectant Devices • Gauze Pads • Electrode Securement Dressings • Cable Securement Dressings • Insertion Needles • iCE-SG2 Electrode Arrays	• Surgical Ruler • Pen • Sterile Drape • Head Drape • Gauze Pads • Electrode Securement Dressings • Trocar sheath tools • Passage assist tools • Exist assist devices • Stoppers • iCE-SG Electrode Arrays
Location of Placement	Subcutaneous space	Subcutaneous space
Method of Placement	Placed using needle	Placed using trocar/sheath
Gauge of Insertion Instrument	14 gauge	11 gauge
Insertion Instrument Material	Stainless steel	Stainless steel
Electrode Configuration	Array	Array
Electrode Material	TPU (Tecoflex)	TPU (Tecoflex)
Contact Number	8	10
Contact Length/Size	2.41 mm	2.41 mm
Contact Spacing	5 mm/10 mm	5 mm/10 mm
Contact Material	Platinum	Platinum
Recording Field Length	66 mm	88 mm
Single Patient Use	Yes	Yes
Disposable	Yes	Yes
Electrode Diameter	1.12 mm	1.12 mm
Overall Depth Length	380 mm	390 mm

	Subject Device	***Predicate Device***
	iCE Neurosystems, Inc. iCE-SG2 Subcutaneous Electrode Kit K222706	iCE Neurosystems, Inc. iCE-SG Subcutaneous Electrode Arrays K201678
Biocompatibility	Per 10993-1	Per 10993-1
Performance Testing	• Cadaver study	• Visual tests • Functional tests • Cadaver study • Animal study
Electrode Sterilization	Ethylene oxide	Ethylene oxide