December 13, 2024

BrainU Co., Ltd.
Yeonwoo Lee
Senior Staff
CTI Co., Ltd.
A-1712, 43, Ilji-ro
Gwangmyeong-si, Gyeonggi-do 14353
Korea, South

Re: K241160
Trade/Device Name: CAIs Sensor (CAIs-001)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 22, 2024
Received: November 22, 2024

Dear Yeonwoo Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241160

Device Name

CAIs Sensor (CAIs-001)

Indications for Use *(Describe)*

The CAIs Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

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) #: K241160

510(k) Summary

Prepared on: 2024-11-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BrainU Co.,Ltd.
Applicant Address	3F, 7, Yatap-ro 105beon-gil, Bundang-gu Seongnam-si Gyeonggi-do 13506 Korea, South
Applicant Contact Telephone	+82 31 707 1788
Applicant Contact	Mr. Sangwoo Choi
Applicant Contact Email	choisw@brainu.co.kr
Correspondent Name	CTI Co.,Ltd.
Correspondent Address	A-1712, 43, Ilji-ro Gwangmyeong-si Gyeonggi-do 14353 Korea, South
Correspondent Contact Telephone	+82 2 6914 5602
Correspondent Contact	Ms. Yeonwoo Lee
Correspondent Contact Email	ywlee@cticert.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CAIs Sensor (CAIs-001)
Common Name	Cutaneous electrode
Classification Name	Electrode, Cutaneous
Regulation Number	882.1320
Product Code(s)	GXY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143506	Covidien BIS Sensors(BIS Quatro Sensor, BIS Extend, BIS Pedi	GXY

Device Description Summary

21 CFR 807.92(a)(4)

The CAIs Sensor, generally speaking with regard to the four variations of the sensor, is a circle shaped, pre-gelled array of four electrodes that is applied to the patient's skin to record electrophysiological signals, such as EEG signals.

It is a low impedance, single patient use, disposable electrode sensor designed for application to the frontal/temporal area. The sensor is designed to provide ease of use and electrode placement accuracy. It is in conjunction with CAIx and CAI software of CAI Monitoring System.

The CAIs sensor is attached to the forehead, and the four electrodes placed on the sensor collect EEG signals and transmit them to the CAI monitoring system through the CAI cable.

Each sensor is packed in individual heat-sealed pouches. Twenty-five (25) sealed pouches are packed into a cardboard box.

The hydrogel used in the sensors is designed for single use by one patient.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CAIs Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both devices are applied directly to the patient's skin to enable the recording of electrophysiological (such as EEG) signals. The CAIs Sensor has substantially the same indications for use as the predicate device (BIS Sensor). The CAIs Sensor is equivalent to the predicate device (BIS Sensor) in terms of the applied site, method of use, material, etc.

Technological Comparison

21 CFR 807.92(a)(6)

Through the above comparison, it was confirmed that the CAIs Sensor has the same major characteristics that affect safety and performance as the preceding device (BIS Sensor). Therefore, we conclude that the CAIs Sensor is as safe and effective as its predecessor (BIS Sensor).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Biocompatibility testing was performed according to the following standard:
10993-1: 2018, 10993-5:2009/(R)2014, 10993-10:2021, 10993-23:2021

Usability engineering, Risk Analysis was performed.
(Performed within the CAI Monitoring System)

Bench testing regarding Electrical, Adhesive Performance, and Shelf Life was performed according to the following:
FDA Guidance "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway"
ANSI/AAMI EC12:2000/(R)2015, IEC 60601-2-2 (2016)

Clinical studies were not performed.

CONCLUSIONS
Based on the results of the non-clinical tests conducted, they demonstrate that the CAIs Sensor (CAIs-001) device is as safe and effective as the current legally marketed predicate device.