March 16, 2023

iMediSync Inc.
Young-Geun Kim
Quality Manager
3F, 175, Yeoksam-ro, Gangnam-gu
Seoul, 06247
South Korea

Re: K222838
Trade/Device Name: iSyncBrain-C
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: December 16, 2022
Received: December 16, 2022

Dear Young-Geun Kim:

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,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D.
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)*
K222838

Device Name
iSyncBrain-C

Indications for Use *(Describe)*
The iSyncBrain-C is to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram (EEG) in patients aged 4.5 to 81 years.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part.
Date: 2022.12.15

I. 510K Applicant / Submitter:

(Legal Manufacturer)
iMediSync Inc.
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Tel: +82-2-747-7422

II. Submission Contact Person (Primary Correspondent Person)

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III. Subject Device

- Trade/Proprietary Name: iSyncBrain-C
- Common Name: Electroencephalograph
- Classification Name: Electroencephalograph, Class II
- Regulation: 21 CFR 882.1400
- Product Code: OLU

IV. Predicate Device

qEEG-Pro (K171414)

V. Description

iSyncBrain-C is a software program for the post-hoc statistical analysis of the human electroencephalogram (EEG).

EEG signals can be measured by various EEG equipment, and the measured EEG data is saved in EDF files. iSyncBrain-C can upload, and analyze these EDF files, and personal information or results are automatically stored in AWS (Amazon Web Serve).

The analysis consists of the Fast-Fourier Transformation (FFT) of the data to extract the spectral power for each of the designated frequency bands (e.g., Delta, Theta, Alpha, Alpha2, Beta, Beta2, Beta3, Gamma) and frequency information from the EEG. These analysis results are displayed in statistical tables and topographical brain maps of absolute and relative power, power ratio, ICA components, power spectrum, occipital alpha peak, source ROI power(sLORETA) & connectivity(iCoh).

All EEG devices has its own frequency characteristics which should be included for any data comparisons coming from different devices. iSyncBrain-C has an EEG amplifier matching module where frequency spectra are adjusted with calibration table between database amplifier and recording amplifier.

In all over 33,000 measures are derived for comparison against carefully constructed and statistically controlled age-regressed, normative database in which the variables have been transformed and validated for their Gaussian distribution.

Each variable extracted by the analysis is compared to the database using parametric statistical procedures that express the differences between the subject and an appropriate sex/age-matched reference group in the form of z-scores.

IV. Indications for Use

The iSyncBrain-C is to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram (EEG) in patients aged 4.5 to 81 years.

VIII. Performance Data

The iSyncBrain-C's software validation was performed in accordance with FDA guidance. The software was tested according to Software Design Specifications(SDS) as intended. The testing results support that all the software specifications have met each module's acceptance criteria and interaction of processes. The iSyncBrain-C passed all testing and supported the claims of substantial equivalence and safe operation. These types of devices, including the predicate devices, have been on the market for many years with proven safety and effectiveness for using the device.

IX. Equivalent device

The information provided in this submission supports that iSyncBrain-C is the substantial equivalence to qEEG-Pro(K171414) and that the system is safe and effective for the

users/operators.

X. Conclusions:

Based on the information provided in this premarket notification, iMediSync Inc. concludes that the iSyncBrain-C is substantially equivalent to the predicate device as described herein in safety and effectiveness.

[Table 1]

Item	Subject Device	Predicate Device 1	Remark
Manufacturer	iMediSync Inc.	Brainmaster Technologies, Inc.	**-**
Product Name	Normalizing Quantitative Electroencephalograph software	Normalizing Quantitative Electroencephalograph software	**-**
Brand Name	iSyncBrain-C	qEEG-pro	**-**
Certification Status	FDA 510(K) / K222838	FDA 510(K) / K171414	**-**
Product code	OLU	OLU	**-**
Classification	CFR 21 882.1400	CFR 21 882.1400	**Equivalent to predicate 1**
OTC and/or Rx	Rx Only	Rx Only	**Equivalent to predicate 1**
Indication of Use	The iSyncBrain-C is to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram (EEG) in patients aged 4.5 to 81 years.	The qEEG-Pro system is to be used by qualified medical and qualified clinical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG).	**Equivalent to predicate 1**
Operating System	Window, Mac Os	Window, Mac Os	**Equivalent to predicate 1**
Indicator	- Absolute power - Relative power - Power ratio - ICA component - Power spectrum - Occipital alpha peak - Source ROI power(sLORETA) & Connectivity (iCoh)	- Absolute power - Relative power - Power ratio - Alpha peak frequency - Asymmetry - Coherence	**Equivalent to predicate 1** The iSyncBrain-C indicators are similar with qEEG-Pro.

Source estimation methods:	• Dipole fit : Yes • Linear inverse methods : sLORETA	• Dipole fit : Yes • Linear inverse methods : sLORETA	**Equivalent to predicate 1** The iSyncBrain-C use the sLORETA for Linear inverse methods.
EEG spectral analysis	8 frequency bands: - Delta (1~4Hz) - Theta (4~8Hz) - Alpha1 (8~10Hz) - Alpha2 (10~12Hz) - Beta1 (12~15Hz) - Beta2 (15~20Hz) - Beta3 (20~30Hz) - Gamma (30~45Hz)	8 frequency bands: - Delta (1~3Hz) - Theta (4~8Hz) - Alpha (8~10Hz) - Alpha2 (10~12Hz) - loBeta (12~15Hz) - Beta (15~20Hz) - hiBeta (20~30Hz) - Gamma (35~45Hz)	**Equivalent to predicate 1** Most gamma frequency bands are 30 -45 Hz, but 30-45 Hz may not be selected according to the manufacturer.
EEG data comparison against Norm DB	Eyes closed (1289 samples) Eyes Open (1288 samples)	Eyes closed (1482 samples) Eyes Open (1231 samples)	**Equivalent to predicate 1** The database size is similar.
Age range included in the Norm DB	4 to 82 years	2 months to 82 years	**Equivalent to predicate 1**