August 10, 2022

iMediSync Inc.
Young-Geun Kim
Deputy Manager
3rd Fl. 175 Yeoksam-ro, Gangnam-gu
Seoul, Korea, 06247

Re: K220056

Trade/Device Name: iSyncWave
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: January 6, 2022
Received: January 6, 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,

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.

510(k) Number *(if known)*
K220056

Device Name

iSyncWave

Indications for Use *(Describe)*

The iSyncWave is intended for prescription use in a health care facility to acquire, transmit, display and store primarily EEG and optional auxiliary signals for adults and children, not including newborns.

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.

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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 807.92
Date: June 30, 2022

I. 510K Applicant / Submitter:

(Legal Manufacturer)
iMediSync Inc.
3rd Fl. 175 Yeoksam-ro, Gangnam-gu, Seoul, Republic of Korea
Tel: +82-2-747-7422

II. Submission Contact Person (Primary Correspondent Person)

Young Geun Kim / Deputy manager
iMediSync Inc.
3rd Fl. 175 Yeoksam-ro, Gangnam-gu, Seoul, Republic of Korea
Tel: +82-2-747-7422
Email: ygkim@imedisync.com

III. Subject Device

- Trade/Proprietary Name: iSyncWave™
- Common Name: Full-montage standard electroencephalograph
- Classification Name: Electroencephalograph
- Regulation: 21 CFR 882.1400
- Product Code: GWQ, GXY

IV. Predicate Device

WR19 System by Zeto Inc. (K172735)

V. Description:

iSyncWave™ is a wireless EEG measurement device that applies dry EEG measurement technology to an international 10-20 system compliant size-adjustable headset.

iSyncWave™ measures 19 channel EEG in real time and transfers the data through BLE wireless connection to the iSyncWave™ App. The data is displayed and recorded via the iSyncWave™ App. iSyncWave™ uses dry electrode technology, which doesn't require a

preparation process(e.g., applying conductive gel), to obtain high quality EEG signals. Before measuring the EEG, you can check the impedance of each electrode under the impedance check screen in the iSyncWave™ app. An EEG amplifier, analog-to-digital converter and Bluetooth are built in the device. All EEG signal is sampled at 250 Hz and then converted to digital data at 24-bit resolution.

This device measures overall EEG data using 19 EEG electrodes, 1 Reference cable and 1 ground electrode. The measured data can be digitally converted to common average, longitudinal and transverse montage. The measured data is automatically uploaded to a secure cloud server via Wi-Fi connection and saved securely. The data saved in the cloud server can be seen on the iSyncWave™ app.

iSyncWave™ can be only used by professional and/or medical personnel with product training and experience in EEG measurement. The professional and/or medical personnel can check the signal quality in real time and refer to the measured data in clinical practice.

IV. Indications for Use

The iSyncWave™ is intended for prescription use in a health care facility to acquire, transmit, display and store primarily EEG and optional auxiliary signals for adults and children, not including newborns.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is substantially equivalent to WR19 System(K172735). The subject device has the same indications for use and the technological characteristics as the predicate device. There are no significant differences between the subject device and predicate device [WR19 System(K172735)]. However, these differences do not raise a question in substantial equivalence discussion. Details refer to “Remark” of below table. Based on the comparison and the performance test data, we conclude that the subject device is substantially equivalent to the predicate device.

VIII. Performance Data

Non-clinical bench tests were performed as followings:

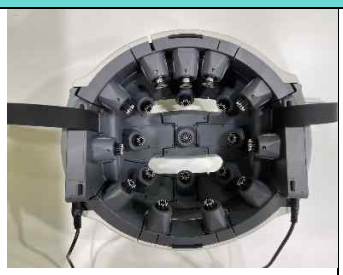
- ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2006/A1:2015 Medical device software - Software life-cycle processes (IEC 62304:2006)
- 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

Along with the above tests, Electromagnetic Compatibility and Electrical Safety, Usability, Biocompatibility, Performance, and software validation were also conducted. None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazard.

X. Conclusions:

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

Item	Predicate Device	Our Device	Remark
Manufacturer	Zeto, Inc.	iMediSync Inc.	-
Product Name	Electroencephalograph	Electroencephalograph	-
Brand Name	WR19 System	iSyncWave™	-

Certification Status	FDA 510(K)/K172735	On going	**-**
[Overview]			
Design			**Equivalent as predicate**
Indications for Use	The WR19 System is intended for prescription use in a health care facility to acquire, transmit, display and store primarily EEG and optional auxiliary signals for adults and children, not including newborns.	The iSyncWave™ is intended for prescription use in a health care facility to acquire, transmit, display and store primarily EEG and optional auxiliary signals for adults and children, not including newborns.	**Same as predicate**
User Interface	Operator control, visual indicators	Operator control, visual indicators	**Equivalent as predicate**
System Components	• Headset • Electrodes • Charger • Charging cable • Software	- Headset - Electrode - Software	**Equivalent as predicate** Charger is not included in the iSyncWave™.
Signals Acquired	• Scalp EEG • Accelerometer	- Scalp EEG	**Equivalent as predicate**
Power Supply	1 x 2050mAh 3.7V Lithium-Ion battery	2950 mAh 3.7V Lithium-Ion battery	**Equivalent as predicate** iSyncWave™ has 50% higher battery capacity.
Battery Charging	Via USB connector connected to USB wall charger.	Via USB connector connected to USB wall charger.	**Equivalent as predicate**
Typical Charging Time	0.5 - 6.0 hours	0.5 - 2.5 hours	**Equivalent as predicate** iSyncWave™ speedy charging.
Operating Time	6 - 7 hours	7 hours	**Equivalent as predicate**
Typical Use Duration	20 - 60 minutes	10 – 20 minutes	**Equivalent as predicate** iSyncWave™ is optimized for quick recording.

Dimensions	8.5 x 10.8 x 5.7" or 214 x 274 x 144 mm (Complete headset with electrodes)	250 x 243 x 150 (mm)	**No significant difference**
Weight	< 650g or 23oz with battery (Complete headset with electrodes)	1.59 kg	**No significant difference** Through complex mechanical structure, stable contact quality is guaranteed.
Cleaning	Cleaned and disinfected by rubbing with isopropyl alcohol	Cleaned and disinfected by rubbing with isopropyl alcohol	**Equivalent as predicate**
[Data Transfer and Storage]			
Internal Data Storage	SD card, Minimum 8GB memory capacity	N/A (No internal data storage)	**No significant difference** iSyncWave™ do not need internal data storage.
File Size per 8 hr Recording	1.5 GB	0.5 GB	**No significant difference** iSyncWave™ use lower data storage.
Wireless Data Transfer	802.11 b/g/n Wi-Fi	BLE V5.0, 802.11 b/g/n Wi-Fi	**No significant difference**
Maximum Wireless Transfer Distance	Headset includes commercially available, FCC-certified, Wi-Fi module that works for standard transfer distance from Wi-Fi Router, typically up to 30 meters.	Headset includes commercially available, FCC-certified, BLE module that works for standard transfer distance from BLE Router, typically up to 10 meters. In order to save the measured data, iSyncWave™ application transfer data via Wi-Fi	**Equivalent as predicate** iSyncWave™ use only BLE and tablet use the Wi-Fi.
[EEG Measurements]			
Definition	Up to 19 referential channels	Up to 19 referential channels	**Equivalent as predicate**
Signal Processing Techniques	Sampling Rate: 500 Hz	Sampling Rate: 250 Hz	**Equivalent as predicate** 250 Hz sample rate is sufficient for routine EEG analysis reviewing delta to gamma (1.0 ~ 50.0 Hz) frequency analysis.
	No hardware LPF/HPF/Notch filters.	Hardware LPF/HPF	**Equivalent as predicate** iSyncWave™'s hardware filter gives cleaner signal to the amplifier.
	Software Filtering: Following are optional:	Software Filtering: 50 Hz, 60 Hz notch filters	**Equivalent as predicate** iSyncWave™ LPF and HPF is

	LPF and HPF (Cutoff frequency selectable by operator), 50 Hz, 60 Hz notch		hardwired while notch filter is implemented on the software.
Accuracy, Performance (EEG)	Sampling rate: 500 Hz Dynamic range: ± 375 mV Resolution: 0.044 µV Peak to peak noise: 4 µV (typical) Common Mode Rejection Ratio: > 120 dB (typical) Input Impedance: 1000 GOhm Noise: 1µV RMS A/D Conversion: 24 Bit	Sampling rate: 250 Hz Dynamic range: ± 1 mV Resolution: 0.3 nV Peak to peak noise: 4 µV (typical) Common Mode Rejection Ratio: > 89 dB (typical) Input Impedance: 1000 GOhm A/D Conversion: 24 Bit	**Equivalent as predicate** Sampling rate: 250 Hz sample rate is sufficient for routine EEG analysis reviewing delta to gamma (1.0 ~ 50 Hz) frequency analysis. - Dynamic Range : iSyncWave™ add an analog front end(AFE) as a preamplifier, on conventional EEG design. The AFE has a gain over a hundred which reduces the dynamic range of the EEG amplifier, but the AFE significantly reduces measurement noises and finally gives a good signal quality. At the same time, even severe abnormal EEG amplitudes are mostly less than ± 1 mV - Resolution: Since the dynamic range is reduced and the signal is quantized by the same 24 bit, the resolution is quite reduced down to 0.1nV. -Common mode rejection: The common mode rejection as a hardware rejection ratio, is less than the predicate device. But iSyncWave™ acquisition software inherently adds another 50/60 Hz notch filter with around 70 dB attenuation for reviewing the EEG in a noisy environment. The notch filter is automatically set by the GPS signal on the acquisition software.
Electrode Type	Active, dry	Dry	**No significant difference** Instead of active electrode, analog front end design is added to the conventional EEG amp.
Contact Quality/ Impedance	Contact quality monitoring performed	Contact quality monitoring performed	**No significant difference**

Measurement	real time throughout the recording/ test	real time throughout the test	During the recording, all computing resource is dedicated to the EEG acquisition.
[Accelerometer]			
Scope of Use	Used primarily as an aid for motion detection and hence finding EEG artifacts	N/A	**No significant difference** Accelerate motion detection is not available.
Channels	Dynamic Range: -180° to 180° Three channels (X, Y, Z) used by software to measure movement and position	N/A	**No significant difference** Same as reason above.
[Software Characteristics]			
Firmware	WR19 headset is controlled by a firmware.	iSyncWave™ headset is controlled by a firmware.	**Equivalent as predicate**
Data Center Application	WR19 sends data to the data center application in the cloud.	iSyncWave™ sends data to the data center application in the cloud.	**Equivalent as predicate**
Client Application	Client application presents waveforms, controls EEG session, and offers standard EEG transformations such as low-pass,high-pass, notch filters and montage transformations.	Client application presents waveforms, controls EEG session, and offers standard EEG transformations such as low-pass,high-pass, notch filters and montage transformations.	**Equivalent as predicate**
	Client application records and retrieves EEG waveforms.	Client application records and retrieves EEG waveforms.	**Equivalent as predicate**
[Reference Device]			
Electrode Material	Ag/AgCl coated	Ag/AgCl coated	**Equivalent as predicate**
Type of Electrodes	Active, dry	Dry	**No significant difference** Instead of active electrode, analog front end design is added to the conventional EEG amp.
Electrode Mounting Mechanism	Semi-rigid wearable headset with certain electrode positions. Electrode positions can be adjusted to a limited extent.	Electrode position can be adjusted to International 10-20 electrode location on the expandable headset structure.	**No significant difference** Special mechanical structure can maintain international 10-20 system during wearing headset and can keep the contact pressure during recording.
Typical Usage Setting	Intended for use for Routine clinical EEG	Intended for use for Routine clinical EEG	**Equivalent as predicate**

	where rapid placement of EEG electrodes as per the 10-20 EEG system is required.	where rapid placement of EEG electrodes as per the 10-20 EEG system is required.	