December 27, 2020

HippoScreen Neurotech Corp.
William Lan
R&D Manager
2F., No. 578, Ruiguang Rd., Neihu District
Taipei City, 11492
Taiwan

Re: K201747
Trade/Device Name: 8-CH Electroencephalography Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, OMC
Dated: November 25, 2020
Received: November 27, 2020

Dear William Lan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201747

Device Name

8-CH Electroencephalography Amplifier

Indications for Use *(Describe)*

The 8-CH Electroencephalography Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals, to transmit them digitally to a computer, and display waveform in real-time. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc). The device is not intended for use in life support systems.

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.

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510(k) Summary

510(k) SUMMARY

1 Type of Submission: Traditional

2 Date of Summary: 06/15/2020

3 Submitter: HippoScreen Neurotech Corp.

Address: 2F., No. 578, Ruiguang Rd., Neihu District, Taipei City 11492, Taiwan, R.O.C
Phone: +886-2-87978060
Fax: +886-2-87978090
Contact: William Lan (william_lan@Hipposcreen-nc.com)

4 Identification of the Device:

Proprietary/Trade name: 8-CH Electroencephalography Amplifier
Classification Product Code:
Primary Product Code: GWL
Additional Product Code: OMC
Regulation Number: 882.1835
Regulation Description: Physiological signal amplifier
Review Panel: Neurology
Device Class: II

5 Identification of the Predicate Device:

Predicate Device Name: eego™ amplifiers
Manufacturer: Eemagine Medical Imaging Solutions GmbH
Classification Product Code:
Primary Product Code: GWL
Additional Product Code: GWQ, OMC
Regulation number: 882.1835

Device Class: II
510(k) Number: K172312

6 Intended Use

Used to electrically amplify signals derived from electroencephalogram.

7 Indications for Use of the Device

The 8-CH Electroencephalography Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals, to transmit them digitally to a computer, and display waveform in real-time. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc). The device is not intended for use in life support systems.

8 Device Description

8-CH Electroencephalography Amplifier capture brain wave signals through non-invasive electrodes, amplify the analog signals and convert to digital signals for computer use. The EEG monitoring panel can immediately display patient's brain wave to assure signal quality of testing requirements. Begin to test when signal quality lamp on EEG monitoring panel shows green light.

9 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, 8-CH Electroencephalography Amplifier.

- Software Validation
- Electromagnetic compatibility and electrical safety
- Performance
- Usability

All the test results demonstrate 8-CH Electroencephalography Amplifier meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

10 Clinical and Usability Testing

No clinical test data was used to support the decision of substantial equivalence.

11 Substantial Equivalence Determination

The 8-CH Electroencephalography Amplifier submitted in this 510(k) file is substantially equivalent in intended use, has similar technology/principles of operation, and similar performance to the cleared eego™ amplifiers (K172312). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item / Feature	Subject device	Predicate device	Substantial equivalence determination
Submitter	HippoScreen Neurotech Corp.	Eemagine Medical Imaging Solutions GmbH	
Proprietary Name	8-CH Electroencephalography Amplifier	eego™ amplifiers	
510(k) No.	K201747	K172312	
Model Name	EAmp-0001	EE-2XX series (EE-211, EE-212, EE-213, EE-221, EE-222, EE-224) and EE-4XX series (EE-411, EE-430)	N/A
Intended Use	Used to electrically amplify signals derived from electroencephalogram.	Used to electrically amplify signals derived from electroencephalogram.	Same. Both devices are amplifiers of EEG signals.

Item / Feature	Subject device	Predicate device	Substantial equivalence determination
Submitter	HippoScreen Neurotech Corp.	Eemagine Medical Imaging Solutions GmbH	
Proprietary Name	8-CH Electroencephalography Amplifier	eego™ amplifiers	
510(k) No.	K201747	K172312	
Indication for Use	The 8-CH Electroencephalography Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals, to transmit them digitally to a computer, and display waveform in real-time. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc). The device is not intended for use in life support systems.	The eego amplifier is intened to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc). The device is not intended for use in life support systems.	Same. Both devices are intended for acquisition of EEG signals to a computer.
Type of use	Prescription Use	Prescription Use	Same
Modes of Operation	Electroencephalography (EEG)	Electroencephalography (EEG)	Same
Environment of Use	Clinical environment (Example: hospital, physician's office, etc)	Clinical environment (Example: hospital, physician's office, etc)	Same
Size	220 x 50 x 153 mm	205 x 22 x 160 mm	Different but does not impact safety and effectiveness of subject device
Weight	600g	< 500g	Different but

Item / Feature	Subject device	Predicate device	Substantial equivalence determination
Submitter	HippoScreen Neurotech Corp.	Eemagine Medical Imaging Solutions GmbH	
Proprietary Name	8-CH Electroencephalography Amplifier	eego™ amplifiers	
510(k) No.	K201747	K172312	
			does not impact safety and effectiveness of subject device
Resolution	24 bit	24 bit	Same
Data Storage	Yes	Yes	Same
Electrode impedance measurement	No	Yes	Different but does not impact safety and effectiveness of subject device
Filter	Low pass filtering in amplifier	Low pass filtering in amplifier	Same
Patient Contact	No Patient contact is made by commercially available electrodes and transducers	No Patient contact is made by the Waveguard™ EEG Cap (K110223).	Same. Both contacts are made by EEG cap.
Sampling rate	500Hz	EE-2XX Series: Up to 16384 Hz Set through the user interface of the Software Development Kit (SDK) software EE-4XX Series: 500 to 2048 Hz	Same as eego EE-430 (EE-430 is 500Hz)
Video	No	Optional	Different but

Item / Feature	Subject device	Predicate device	Substantial equivalence determination
Submitter	HippoScreen Neurotech Corp.	Eemagine Medical Imaging Solutions GmbH	
Proprietary Name	8-CH Electroencephalography Amplifier	eego™ amplifiers	
510(k) No.	K201747	K172312	
			does not impact safety and effectiveness of subject device
Amplifier active shielding technique	Yes (Protects the referential EEG inputs from environmental noise)	Yes (Protects the referential EEG inputs from environmental noise)	Same
Amplifier CMRR (referential)	94 db at dc to 60 Hz	>100 dB	Similar (Subject device had meet the requirement of IEC 60601-2-26)
Amplifier Input Channels	8	Up to 64	Same as eego EE-430
Amplifier input impedance (referential)	$>10^9\,\Omega$	$>10^9\,\Omega$	Same
Amplifier power	AC input 100V~240V, 50-60Hz DC output 5V/ 2.0A	EE-2XX Series: Rechargeable integrated battery EE-4XX Series: USB from Computer	Different but does not impact safety and effectiveness of subject device
Amplifier operating time on	Not applicable	EE-2XX Series: Up to 4 hours	Different but does not impact

Item / Feature	Subject device	Predicate device	Substantial equivalence determination
Submitter	HippoScreen Neurotech Corp.	Eemagine Medical Imaging Solutions GmbH	
Proprietary Name	8-CH Electroencephalography Amplifier	eego™ amplifiers	
510(k) No.	K201747	K172312	
battery power			safety and effectiveness of subject device
Amplifier referential DC input channels	8	Yes 8, 16, 32, or 64 channels	Same as eego EE-430
Amplifier trigger input	No	Yes, EE-2XX Series: Optional 8 bit TTL EE-4XX Series: Optional 2 bit TTL	Different but does not impact safety and effectiveness of subject device
Amplifier trigger input channel	No	Yes (Parallel)	Different but does not impact safety and effectiveness of subject device
Amplifier USB interface	Yes	Yes	Same
Safety standards applied	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 62133	Similar (Appropriate standards are applied on the subject device.)

12 Similarity and Difference

The 8-CH Electroencephalography Amplifier has been compared with eego™ amplifiers. The subject device and predicate device has same intended use, indication for use, type of use, modes of operation, environment of use, resolution, data storage function, filter, patient contact, sampling rate, amplifier active shielding technique, amplifier input channels, amplifier input impedance (referential), amplifier referential DC input channels, and amplifier USB interface.

Although there are some functions that are different between two devices, such as electrode impedance measurement, video function, amplifier power, amplifier trigger input function, and amplifier input channel, the function of subject device did not exceed that of the predicate device. Also, performance tests have been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device.

As for amplifier CMRR (referential), subject device is a little bit lower than that of the predicated device. However, subject device had met the requirement of IEC 60601-2-26.

In conclusion, the subject device has undergone safety and performance tests, and the results complied with the test requests; therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

13 Conclusion

In conclusion, HippoScreen Neurotech Corp. believes that 8-CH Electroencephalography Amplifier maintains the same safety and effectiveness, and thus, is substantially equivalent to the predicate device.