March 30, 2018
eemagine Medical Imaging Solutions GmbH
% Gary J. Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K172312
Trade/Device Name: eego amplifiers
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GWQ, OMC
Dated: July 25, 2017
Received: March 1, 2018

Dear Gary J. Syring:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.03.30 16:43:21 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172312

Device Name
eego™ amplifiers

Indications for Use *(Describe)*
The eego amplifier is intended 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.

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."

K173312 510(k) Summary

Submitter Information

Submitter's Name:	eemagine Medical Imaging Solutions GmbH
Submitter's Address:	Gubenerstr. 47, Fabrik D-10243, Berlin, Germany
Submitter's Phone:	Phone: +49 30 29 04 84 04
Contact Person:	Frank Zanow, Chief Executive Officer or Ralf Hauffe, PhD, Chief Operations Executive Officer
Date Summary Prepared:	March 29, 2018

Subject Device

Trade Name:	eego™ amplifiers
Common Name:	Physiological signal amplifier
Classification Name:	21 CFR 882.1835 Physiological signal amplifier Class II
Product Code:	GWL, amplifier, physiological signal
Subsequent Code:	GWQ, full-montage standard electroencephalograph OMC, reduced- montage standard electroencephalograph

Predicate Device

510(k) Number:	K060374
Trade Name:	REFA, Physiological Amplifier
Submitter Name:	TMS International BV
Classification Name:	21 CFR 882.1835
Product Code:	GWL

Device Description

The eego amplifier is a multi-channel, plastic enclosed EEG amplifier. There are two ranges for the variations of amplifiers (models):

1. EE-2xx, and
2. EE-4xx.

In total, there are 8 models, as follows:

Model	EEG Channels (Referential)	Sampling rate configuration (down sampling in API software, internal 32 kHz for all)	Power Source
EE-211	64	2 kHz	Rechargeable battery
EE-212	32	2 kHz	
EE-213	16	2 kHz	
EE-221	32	16 kHz	
EE-222	64	16 kHz	
EE-224	32	16 kHz	
EE-411	8	2 kHz	USB Connection to Computer
EE-430	8	0.5 kHz	

The EE-411 and EE-430 amplifiers are built using identical components and share identical internal structure, functionality and performance.

The eego amplifier electroencephalography (EEG) input is from commercially available EEG electrodes from the Waveguard™ EEG Cap cleared in K110223.

The eego amplifiers support EEG acquisition and storage by:

1. referential DC input channels,
2. parallel trigger input channel.

Electrode Impedance values can be measured for all referential electrodes, reference and patient ground electrode. Signal sampling rate and gain are set through the user interface of the Software Development Kit (SDK).

The EE-2XX series of eego amplifier is powered by a built-in, rechargeable battery. The battery provides a minimum of 4 hours of operation time. The amplifier can be applied for data acquisition with the 12 V battery charger source applied. The USB port supports interface to the computer running the SDK.

The EE-4XX series of eego amplifier is powered by the USB port connection to a computer.

Statement of Intended Use

The eego amplifier is intended 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.

Summary of Technological Characteristics & Comparison to Predicate

The following table provides a comparison the eego amplifiers to the predicate device identified to demonstrate substantial equivalence.

Table 1: Substantial Equivalence Technical Characteristics

Feature	eego™ amplifiers Subject Device K172312	REFA Physiological Amplifier Predicate K060374	Comment
Intended Use	Used to electrically amplify signals derived from electroencephalogram.	Used to electrically amplify signals derived from various physiological sources, including the electroencephalogram.	Both devices are amplifiers of signals derived from physiologic sources.
Indications for Use	The eego amplifier is intended 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.	The REFA Physiological Amplifier family is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of the signals to a PC during recording of neurophysical / physiological research and exams. Polygraphy and Polysomnography may besides EEG, include physiological information such as EMG, ECG, EOG, EGG, PH, Respiration, Temperature and Oxygen Saturation.	Amplifiers are intended for acquisition of EEG signals to a computer.
Type of use	Prescription Use	Prescription Use	Same
Modes of Operation	Electroencephalography (EEG)	EEG, EMG, ECG, EOG EGG, PH Respiration, Temperature,	Both acquire EEG signals.

Table 1: Substantial Equivalence Technical Characteristics			
Feature	**eego™ amplifiers Subject Device K172312**	**REFA Physiological Amplifier Predicate K060374**	**Comment**
		Oxygen Saturation	
Environment of Use	Clinical environment (Example: hospital, physician's office, etc)	Clinical environment (Example: hospital, physician's office, etc)	Same
Data Storage	Yes	Yes	Same
Electrode impedance measurement	Yes	Yes	Same
Filter	Low pass filtering in amplifier	Low pass filtering in amplifier	Same
Patient Contact	No Patient contact is made by the Waveguard™ EEG Cap (K110223).	No Patient contact is made by commercially available electrodes and transducers.	Equivalent
Sampling rate	EE-2XX Series: Up to 16384 Hz Set through the user interface of the Software Development Kit (SDK) software EE-4XX Series: Up to 2048 Hz	Up to 20000 Hz	Equivalent
Video	Optional	No	Option to allow video
Amplifier active shielding technique	Yes (Protects the referential EEG inputs from environmental noise)	Yes	Same
Amplifier CMRR (referential)	>100 dB	90 dB	Equivalent
Amplifier Input Channels	Up to 64	Up to 64 Special mode supports 128 EEG inputs	Equivalent
Amplifier input impedance (referential)	$>10^9$ Ohm	$>10^{12}$ Ohm	Equivalent for low impedance of physiological signal inputs.
Amplifier power	EE-2XX Series: Rechargeable integrated battery EE-4XX Series: USB from Computer	AC Mains	DC power source for eego amplifiers.
Amplifier operating time on battery power	EE-2XX Series: Up to 4 hours	Not Applicable	DC power source for eego amplifiers.
Amplifier referential DC input channels	Yes 8, 16, 32, or 64 channels	Yes 16, 32, 64 or 128 channels	Equivalent
Amplifier trigger input	Yes, EE-2XX Series: Optional 8 bit TTL EE-4XX Series: Optional 2 bit TTL	Yes, Optional 8 bit TTL	Equivalent
Amplifier trigger input channel	Yes (Parallel)	Yes	Equivalent
Amplifier USB interface	Yes	Yes	Same

Table 1: Substantial Equivalence Technical Characteristics			
Feature	**eego™ amplifiers Subject Device K172312**	**REFA Physiological Amplifier Predicate K060374**	**Comment**
Safety standards applied	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 62133	IEC 60601-1 IEC 60601-1-2	Appropriate standards applied

Performance Testing

To establish the equivalency of the eego amplifiers, evaluations were conducted to confirm compliance with performance requirements and standards including:

- IEC 60601-1:2005 (DIN EN 60601-1:2007), Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-26: 2012 Medical electrical equipment, Particular requirements for the basic safety and essential performance of electroencephalographs.
- IEC 62133 Edition 2.0 2012-12, Secondary cells and batteries containing alkaline or other non-acid electrolytes - safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

Conclusion

The eego amplifiers meet performance requirements equivalent to the predicate device. The intended use and technology of the eego amplifiers are equivalent to the predicate device.