January 30, 2020

eemagine Medical Imaging Solutions GmbH
% Mr. Steve Hesler
Consultant
S. Hesler Compliance Engineering
2602 5th Avenue
West Linn, Oregon 97068

Re: K192889
Trade/Device Name: nëo Monitor System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMA, ORT, OMC
Dated: November 11, 2019
Received: November 13, 2019

Dear Mr. Steve Hesler:

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,

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)*
K192889

Device Name
nëo™ Monitor System

Indications for Use *(Describe)*
The nëo monitor is an 8-channel electroencephalograph (EEG) acquisition software. The device is intended to record and display EEG and aEEG signals for monitoring the brain status of neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks). The device is to be used in a hospital environment by qualified clinical practitioners. The device does not provide any diagnostic conclusion about the patient's condition to the user.

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
(per 21 CFR 807.92)

Date prepared:
January 19, 2020

Submitter:
eemagine Medical Imaging Solutions GmbH
Gubener Str. 47,
D-10243 Berlin, Germany
Phone: +49 (0)30 2904 8404
E-Mail: support@eemagine.com

Contact person:
Steve Hesler
503 260 8221
heslers@yahoo.com

Proprietary name:
nëo™ Monitor System

Common name:
Electroencephalograph

Classified name:
Reduced- Montage Standard Electroencephalograph
CFR 882.1400
Product code: OMC
Class 2

Amplitude-Integrated Electroencephalograph
CFR 882.1400
Product code: OMA
Class 2

Burst Suppression Detection Software for Electroencephalograph
CFR 882.1400
Product code: ORT
Class 2

Indications for use:
The nëo™ monitor is an 8-channel electroencephalograph (EEG) acquisition software. The device is intended to record and display EEG and aEEG signals for monitoring the brain status of neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks). The device is to be used in a hospital environment by qualified clinical practitioners. The device does not provide any diagnostic conclusion about the patient's condition to

the user.

Description of device:

The nëo™ system is a reduced montage neonatal electroencephalograph device that acquires, displays, stores, and archives electroencephalographic signals from the brain. By application of electrodes at specific location on the cranium,using up to 10 surface electrodes placed at specific locations the system functions to measure and record electrical activity of the brain by acquisition of electroencephalograph data and amplitude-integrated electroencephalograph (electroencephalograph signals that have been filtered and displayed in a specific manner).

The nëo System is an electromedical device incorporating software. The device itself has no patient contact, but is intended for use with FDA-cleared ECG electrodes. nëo™ Monitor software, which, when installed into a compatible touch-screen PC and paired with a physiological signal amplifier (eego model EE-411) forms the nëo™ Monitor System. The system is a compact and easy-to-use and can be set on a bedside table, pole-mounted, or on a cart in the neonatal care areas.

The system, as-delivered to the customer, is comprised of:

- nëo Monitor software (pre-installed)
- 15” Panel PC
- eego EE-411 model amplifier
- Mounting plate
- nëo User Manual

Substantial equivalence:

The nëo™ system is substantially equivalent to the Olympic Brainz Monitor (K093949, June 16, 2010).

Summary of technological characteristics compared to predicate devices:

Device Feature	nëo™	Olympic Brainz Monitor
Reduced montage EEG (code OMC)	Yes	Yes
Amplitude integrated electroencephalograph (code OMA)	Yes	Yes
Burst suppression detection software (code ORT)	Burst suppression ratio (BSR) Inter burst Interval (IBI)	No
Target population	Neonates	Neonates
Use environment	neonatal care areas	NICU/research
Access	Roll-pole mount, cart mount	Roll-pole
Power Supply	100-240V /50/60 Hz	100 - 240 VAC, 50/60 Hz
Display/user interface	15” touchscreen	15” touchscreen
Mount	Vesa 100 interface	Vesa interface
Number of channels	8 max	3 max
Sampling rate	512 Hz	2000 Hz

Sampling resolution	24 bit	16 bits @2000 Hz
Input impedence	>1 GΩ	>50MΩ
Bandwidth:	0Hz -128Hz	0.5Hz ~ 450Hz
Noise in bandwidth	< 1.4μVrms for a bandwidth of 0Hz - 128Hz	< 1 μV (RMS) (@450Hz bandwidth)
Secondary parameters	None	None
Signal reliability parameters	Notification messages for high impedance (>100kOhm) and non-physiological data (saturated channel, strong drift, and strong hum noise)	Continuous Impedance values/trace
Patient identification data	Shows Patient name, ID, Date of birth, Gender, Gestational age at birth	Shows patient name, date of birth, time of birth and ID
Event marking ·	Yes, User can insert default or user- defined markers during the recording	Yes. User can mark areas of interest.
Recorded file reviewing.	Yes	Yes
Working memory	8 GB	2 GB
Data export / storage:	via USB port	via USB port
Software upgrades:	via USB port	CD ROM drive
Simultaneous and synchronized aEEG and raw EEG display	Yes	Yes
Shows Impedance measurements	Yes	Yes
aEEG signal processing algorithm	Filtered by aEEG filter, rectified and semi logarithmically compressed	Filtered by aEEG filter, rectified and semi logarithmically compressed
aEEG filter specification	Expected aEEG values for sine wave input signals of 100μVpp: Frequency (Hz) | aEEG value μV --- 2Hz | 23μV 10Hz | 100μV 14Hz | 100μV 25Hz | 14μV	Up to 2 Hz: Rising by 60 dB/decade 2 Hz - 12 Hz: Rising by 12 dB/decade 12 Hz - 16 Hz: 1 dB above 10 Hz level 16 Hz - 30 Hz: cut off slope 120 dB/decade 50 Hz and above: 60 dB down on 10 Hz response
aEEG display scale	Semi logarithmic scale from 0 to 100 micro Volts	Semi logarithmic scale from 0 to 100 micro Volts.
Number of electrodes	8 active electrodes + 1 reference + 1 patient ground	4 active electrodes + 1 • reference

nëo™monitor software is also compared with the Background Pattern Classification software (BPc) released by Natus Medical (K152301). Both software packages employ burst suppression algorithms.

Non-Clinical Testing:

The nëo has been developed and tested to the following standards:

- IEC 60601-1: Medical Electrical Equipment - PART 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-2-26: Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 62304 - Medical Device Software - Software Life Cycle Processes
- ISO 14971 - Medical Devices - Application of Risk Management to Medical Devices

Conclusion:

Based on the above comparison it is determined that the nëo™ system is substantially equivalent to the predicate Olympic Brainz Monitor.