January 22, 2020

Joel Kent
Senior Regulatory Affairs Manager
GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki, Finland

Re: K191322
Trade/Device Name: E-EEGX module, N-EEGX headbox and accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GWJ, MHX, MLD, OMC, ORT
Dated: December 19, 2019
Received: December 23, 2019

Dear Joel Kent:

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)*
K191322

Device Name
E-EEGX module, N-EEGX headbox and accessories

Indications for Use *(Describe)*
The GE EEG module, E-EEGX, the GE EEG headbox, N-EEGX, and accessories are intended to be used with the compatible CARESCAPE monitors for the monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG), and auditory evoked potentials (AEP) of all hospital patients. The device is intended for use by qualified medical personnel only.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1):

Date: January 16, 2020

Owner/Submitter: GE Healthcare Finland Oy.
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Device names (807.92(a)(2)):

Trade Name: E-EEGX module, N-EEGX headbox and accessories

Common/Usual Name: EEG measurement module, headbox and accessories

Classification Name: 21 CFR 882.1400 electroencephalograph

Product Code	OLT
Subsequent Product Codes:	GWJ, MHX, MLD, OMC, ORT
Predicate Device(s) (807.92(a)(3):	K051883 Datex-Ohmeda S/5 EEG Module, E-EEG and Datex-Ohmeda S/5 EEG Headbox, N-EEG and Accessories
Device Description (807.92(a)(4)):	The E-EEGX module is a single-width plug-in interface module to be used with CARESCAPE Bx50 V3 patient monitors. It is used with N-EEGX headbox and accessories for monitoring neurophysiological status of all hospital patients by measuring the electroencephalogram (EEG), frontal electromyogram (FEMG) and auditory evoked potentials (AEP).
Intended Use: (807.92(a)(5):	The GE EEG module, E-EEGX, the GE EEG headbox, N-EEGX, and accessories are intended to be used with the compatible CARESCAPE monitors for the monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG), and auditory evoked potentials (AEP) of all hospital patients. The device is intended for use by qualified medical personnel only.
Technology (807.92(a)(6)):	The E-EEGX module is used with the N-EEGX headbox for monitoring of EEG, FEMG, to stimulate the brain with auditory stimuli, and to measure AEP. The E-EEGX module connects to a N-EEGX headbox which further connects to accessories that connect to the patient. The EEG, FEMG and AEP measurements are performed by the N-EEGX headbox. The N-EEGX headbox measures the raw EEG waveform data from four real-time EEG waveform channels, FEMG from one channel and AEP from two channels. The N-EEGX headbox is connected to the patient with EEG accessories. The E-EEGX module transfers the digitized EEG data received from the N-EEGX headbox to the host monitor. The module also generates the stimuli used in the AEP measurement and performs part of the AEP measurement data processing. The fundamental function and operation of the device remains unchanged compared to the predicate. A summary of the main changes compared to the predicate is listed below.

Specification	Datex-Ohmeda S/5 EEG Module, E-EEG and Datex-Ohmeda S/5 EEG Headbox, N-EEG and Accessories (K051883)	E-EEGX module, N-EEGX headbox and EEG accessories	Discussion of differences
Indications for use	The Datex-Ohmeda EEG module, E-EEG and the Datex-Ohmeda EEG headbox, N-EEG and accessories are indicated for monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG) and auditory evoked potentials (AEP) of all hospital patients. The device is indicated for use by qualified medical personnel only.	The GE EEG module, E-EEGX, the GE EEG headbox, N-EEGX, and accessories are intended to be used with the compatible CARESCAPE monitors for the monitoring of electroencephalograph (EEG), frontal electromyograph (FEMG), and auditory evoked potentials (AEP) of all hospital patients. The device is intended for use by qualified medical personnel only.	Equivalent The changes from previously cleared indications are: Company name "Datex" has been replaced by "GE". The indications refer to compatible monitors. Some minor text edits and changes for added clarity. The changes have been made to improve clarity of labeling. Therefore, they do not significantly affect safety and/or effectiveness.
Physical Properties Module Size(H x W x D) Module Weight	E-EEG module 112 x 37 x 186 mm (4.4 x 1.5 x 7.3 in) 0.3 kg (0.7 lb) N-EEG headbox 34 x 97 x 174 mm (1.3 x 3.8 x 6.8 in) 0.44 kg (1.1 lb)	E-EEGX module 112 x 37 x 187 mm (4.4 x 1.5 x 7.3 in) 0.3 kg (0.7 lb) N-EEGX headbox 34 x 97 x 174 mm (1.3 x 3.8 x 6.8 in) 0.5 kg (1.1 lb)	Equivalent The N-EEGX headbox weight has slightly changed due to a new hardware design. This change does not significantly affect safety and/or effectiveness.
Host device compatibility	E-EEG module is compatible with S/5 AM, CAM, S/5 CCM, CARESCAPE B450 Monitor with software ESP V1 or V2, CARESCAPE Monitor B650 with software ESP V1 or V2 and CARESCAPE Monitor B850 with software ESP V1 or V2	E-EEGX module and N-EEGX headbox are compatible with the CARESCAPE Bx50 V3 patient monitors	Equivalent The E-EEGX module and N-EEGX headbox are only compatible with CARESCAPE Bx50 V3 patient monitors. This change has been verified and the overall functionality remains equivalent. This change does not significantly affect safety and/or effectiveness.
Parameter Specifications			
Measured parameters	EEG, Auditory Evoked Potentials, EMG	EEG, Auditory Evoked Potentials, EMG	Identical
Mode	Referential or Bipolar	Referential or Bipolar	Identical
Processing of the EEG	Spectral analysis: Spectral Edge Frequency (SEF), Median frequency, Relative power in Delta, Theta, Alpha and Beta bands Burst suppression detection Total power	Spectral analysis: Spectral Edge Frequency (SEF), Median frequency, Relative power in Delta, Theta, Alpha and Beta bands Burst suppression detection Total power	Identical
EEG parameter specifications			
EEG Measurement method	1, 2, 3 or 4 channels of EEG	1, 2, 3 or 4 channels of EEG	Identical
Range	± 400 µV	± 500 µV	Equivalent Range has been expanded to meet the requirements of IEC 60601-2-26:2012. This change has been verified and the overall functionality remains equivalent. This change does not significantly affect safety and/or effectiveness.
Measurement range frequency	0.5 … 30 Hz	0.5 … 50 Hz	Equivalent Range has been expanded to meet the requirements of IEC 60601-2-26:2012. This change has been verified and the overall functionality remains equivalent. This change does not significantly affect safety and/or effectiveness.

AEP parameter specifications			
Evoked potentials	Auditory evoked potentials: brain stem and mid-latency	Auditory evoked potentials: brain stem and mid-latency	Identical
Measurement Sampling frequency	Brainstem Auditory Evoked Potentials (BAEP): 4800 Hz Middle Latency Auditory Evoked Potential (MLAEP): 2400 Hz	Brainstem Auditory Evoked Potentials (BAEP): 4800 Hz Middle Latency Auditory Evoked Potential (MLAEP): 2400 Hz	Identical
Frequency range	0.5 Hz – 1000 hz	0.5 Hz – 1000 Hz	Identical
Stimulation type	Condensating click	Condensating click	Identical
Stimulation frequency	1.1 to 9.1 Hz (1 Hz steps) @ 10 ms sweep 1.1 to 8.1 Hz (1 Hz steps) @ 100 ms sweep	1.1 to 9.1 Hz (1 Hz steps) @ 10 ms sweep 1.1 to 8.1 Hz (1 Hz steps) @ 100 ms sweep	Identical
EMG parameter specifications			
EMG measurement frequency range	60 to 300 Hz	60 to 300 Hz	Identical

Determination of Substantial Equivalence (807.92(b)(1))

Summary of Non-Clinical Tests:

For the E-EEGX module, N-EEGX headbox and accessories the following quality assurance measures were applied to the development of the system.

1. Risk Analysis
2. Requirements Reviews
3. Design Reviews
4. Testing on unit level (Module verification)
5. Integration testing (System verification)
6. Final acceptance testing (Validation)
7. Performance testing (Verification)
8. Safety testing (Verification)

9. The following list contains applicable standards regarding performance testing related to E-EEGX module, N-EEGX headbox and accessories:

    - ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012: Medical electrical equipment Part 1: General requirements for basic safety and essential performance (IEC 60601-1: 2012)
    - IEC 60601-1-2: 2014: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
    - IEC 60601-2-26:2012: Medical electrical equipment Part 2-26: Particular requirements for

the safety and essential performance of electroencephalographs

- IEC 60601-2-40: 2016: Medical Electrical Equipment Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC 60601-2-49: 2011: Medical electrical equipment Part 2-49: Particular requirements for the safety essential performance of multifunction patient monitoring equipment

Clinical (807.92(b)(2)): Summary of Clinical Tests:

The subject of this premarket submission, the E-EEGX module, N-EEGX headbox and accessories did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the E-EEGX module, N-EEGX headbox and accessories to be as safe, as effective, and performance is substantially equivalent to the predicate device.