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
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/combo...

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.


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 R. Gupta -S

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
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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. Kuortaneenkatu 2 00510 Helsinki FINLAND Phone: +358 10 39411

Primary Contact Person: Joel Kent
Senior Regulatory Affairs Manager
GE Healthcare
Phone: 617-851-0943
E-mail: joel.kent@ge.com

Secondary Contact Person: Anna Pehrsson
Regulatory Affairs Leader
GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland
Phone: + 358 40 569 5108
E-mail: anna.pehrsson@ge.com

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.
**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.

**Physical Properties**

### Module Size (H x W x D)

<table>
<thead>
<tr>
<th></th>
<th>E-EEG module</th>
<th>E-EEGX module</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>112 x 37 x 186 mm (4.4 x 1.5 x 7.3 in)</td>
<td>112 x 37 x 187 mm (4.4 x 1.5 x 7.3 in)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N-EEG headbox</th>
<th>N-EEGX headbox</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>34 x 97 x 174 mm (1.3 x 3.8 x 6.8 in)</td>
<td>34 x 97 x 174 mm (1.3 x 3.8 x 6.8 in)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>0.3 kg (0.7 lb)</th>
<th>0.3 kg (0.7 lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.44 kg (1.1 lb)</td>
<td>0.5 kg (1.1 lb)</td>
</tr>
</tbody>
</table>

**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

**Parameter Specifications**

**Measured parameters**

- EEG, Auditory Evoked Potentials, EMG
- EEG, Auditory Evoked Potentials, EMG

**Mode**

- Referential or Bipolar
- Referential or Bipolar

**Processing of the EEG**

- Spectral analysis: Spectral Edge Frequency (SEF), Median frequency, Relative power in Delta, Theta, Alpha and Beta bands
- Spectral analysis: Spectral Edge Frequency (SEF), Median frequency, Relative power in Delta, Theta, Alpha and Beta bands

- Burst suppression detection
- Burst suppression detection

- Total power
- Total power

**EEG parameter specifications**

**EEG Measurement method**

- 1, 2, 3 or 4 channels of EEG
- 1, 2, 3 or 4 channels of EEG

**Range**

- ± 400 µV
- ± 500 µV

**Measurement range frequency**

- 0.5 … 30 Hz
- 0.5 … 50 Hz
AEP parameter specifications

<table>
<thead>
<tr>
<th></th>
<th>Auditory evoked potentials: brain stem and mid-latency</th>
<th>Auditory evoked potentials: brain stem and mid-latency</th>
<th>Identical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency range</td>
<td>0.5 Hz – 1000 Hz</td>
<td>0.5 Hz – 1000 Hz</td>
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</tr>
<tr>
<td>Stimulation type</td>
<td>Condensating click</td>
<td>Condensating click</td>
<td>Identical</td>
</tr>
<tr>
<td>Stimulation frequency</td>
<td>1.1 to 9.1 Hz (1 Hz steps) @ 10 ms sweep</td>
<td>1.1 to 9.1 Hz (1 Hz steps) @ 10 ms sweep</td>
<td>Identical</td>
</tr>
<tr>
<td></td>
<td>1.1 to 8.1 Hz (1 Hz steps) @ 100 ms sweep</td>
<td>1.1 to 8.1 Hz (1 Hz steps) @ 100 ms sweep</td>
<td>Identical</td>
</tr>
</tbody>
</table>

EMG parameter specifications

<table>
<thead>
<tr>
<th></th>
<th>60 to 300 Hz</th>
<th>60 to 300 Hz</th>
<th>Identical</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMG measurement frequency range</td>
<td></td>
<td></td>
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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:

   - IEC 60601-2-26:2012: Medical electrical equipment Part 2-26: Particular requirements for
the safety and essential performance of electroencephalographs


**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.