



March 14, 2018

Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)  
Sanjay Mehta  
Director Regulatory Affairs  
2568 Bristol Circle  
Oakville, L6H 5S1 CA

Re: K180421  
Trade/Device Name: Natus NeuroWorks  
Regulation Number: 21 CFR 882.1400  
Regulation Name: Electroencephalograph  
Regulatory Class: Class II  
Product Code: OMB, OMA, OLT  
Dated: February 15, 2018  
Received: February 16, 2018

Dear Sanjay Mehta:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Michael J. Hoffmann -S**

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

## Indications for Use

510(k) Number (if known)  
K180421

Device Name  
Natus NeuroWorks

### Indications for Use (Describe)

The NeuroWorks is EEG software that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

- The NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals.
- The Seizure Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- The Spike Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- The aEEG functionality included in NeuroWorks is intended to monitor the state of the brain. The automated event marking function of NeuroWorks is not applicable to aEEG.
- NeuroWorks also includes the display of a quantitative EEG plot, Compressed Spectrum Array (CSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of NeuroWorks is not applicable to CSA.

This 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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*"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."*

**Submission Date:** 13 March 2018

**Submitter:** Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)  
2568 Bristol Circle  
Oakville, Ontario, L6H 5S1  
Canada

**Submitter and Application Correspondent:** Mr. Sanjay Mehta  
Phone: +1 (905) 287-5055  
Fax: +1 (905) 829-5304  
Email: [sanjay.mehta@natus.com](mailto:sanjay.mehta@natus.com)

**Manufacturing Site:** Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)  
2568 Bristol Circle  
Oakville, Ontario, L6H 5S1  
Canada

**Trade Name:** Natus NeuroWorks

**Common and Classification Name:** Automatic Event Detection Software For Full-Montage Electroencephalograph

**Classification Regulation:** 21 CFR §882.1400

**Product Code:** OMB (primary), OMA, OLT

<b>Substantially Equivalent Devices:</b>	<i>New Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
	NeuroWorks	K090019	Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle Oakville, Ontario, L6H 5S1 Canada

**Device Description:** Natus NeuroWorks is electroencephalography (EEG) software that displays physiological signals. The software platform is designed to work with Xltek and other select Natus amplifiers (headboxes). Software add-ons and optional accessories let you customize your system to meet your specific clinical EEG monitoring needs.

***Intended Use:***

The NeuroWorks is EEG software that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

- The NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals.
- The Seizure Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- The Spike Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- The aEEG functionality included in NeuroWorks is intended to monitor the state of the brain. The automated event marking function of NeuroWorks is not applicable to aEEG.
- NeuroWorks also includes the display of a quantitative EEG plot, Compressed Spectrum Array (CSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of NeuroWorks is not applicable to CSA.

This device does not provide any diagnostic conclusion about the patient's condition to the user.

**Technology Comparison:**

The NeuroWorks employs the same technological characteristics as the predicate device.

<i>System Characteristic</i>	<b><i>Natus Medical Inc DBA Excel-Tech Ltd. Natus NeuroWorks (K090019)</i></b>	<b><i>Natus Medical Incorporated DBA Excel-Tech Ltd. Natus NeuroWorks (Proposed Device)</i></b>
<i>Intended Use</i>	<p>The NeuroWorks is EEG software that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.</p> <p>The NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals. The Seizure Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. The Spike Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. The aEEG functionality included in NeuroWorks is intended to monitor the state of the brain. The automated event marking function of NeuroWorks is not applicable to aEEG.</p> <p>NeuroWorks also includes the display of a quantitative EEG plot, Compressed Spectrum Array (CSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of NeuroWorks is not applicable to CSA.</p> <p>This device does not provide any diagnostic conclusion about the patient's condition to the user.</p>	Same.
<i>Personal Computer Operating System</i>	Microsoft® Windows XP	Microsoft® Windows 7 Microsoft® Windows 10

<i>System Compatibility (for using NeuroWorks during cortical stimulation procedures only)</i>	None	Natus Quantum amplifier in conjunction with Nicolet Cortical Stimulator Control Unit
<i>Cortical Stimulation</i>	External stand-alone device	Yes, Nicolet Cortical Stimulator controlled from NeuroWorks software in conjunction with stimulus switching.

**Summary of Performance Testing:**

*Software*

The NeuroWorks software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following FDA guidance documents and standards:

- *The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *Off-the-shelf software use in medical devices, 09 Sep 99.*
- *General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 Jan 05*
- *IEC 62304: 2006, Medical device software – Software life cycle processes*

Results indicate that the NeuroWorks software complies with its predetermined specifications, the applicable guidance documents, and the applicable standards.

*Performance Testing – Bench*

The NeuroWorks software was verified for performance in accordance with internal requirements and the applicable clauses of the following standards:

- *IEC 60601-1-6: 2010, Am1: 2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
- *IEC 62366: 2007, Am1: 2014, Medical devices – Application of usability engineering to medical devices.*

Results indicate that the NeuroWorks software complies with its predetermined specifications and the applicable standards.

## ***Conclusion***

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the NeuroWorks software. The results of these activities demonstrate that the NeuroWorks software is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the NeuroWorks software is considered substantially equivalent to the predicate device.