



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 14, 2016

Natus Medical Incorporated DBA Excel-tech Ltd. (XLTEK)
Mr. Sanjay Mehta
Senior Manager, Quality Assurance & Regulatory Affairs
2568 Bristol Circle
Oakville, Ontario, L6H 5S1
Canada

Re: K163163

Trade/Device Name: XLTEK EMU40EX EEG Headbox
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: November 3, 2016
Received: November 10, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

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)

K163163

Device Name

XLTEK EMU40EX EEG Headbox

Indications for Use (Describe)

The XLTEK EMU40EX EEG Headbox is an electroencephalograph that works in conjunction with XLTEK NeuroWorks software.

The XLTEK EMU40EX EEG Headbox is used to acquire, digitize, store and transmit physiological signals (such as EEG, pulse and oximetry signals) for EEG studies in research and clinical environments.

The XLTEK EMU40EX EEG Headbox requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgment in using this information.

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
PRASStaff@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."

510(k) Summary

Submission Date: 03 November 2016

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

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

Trade Name: XLTEK EMU40EX EEG Headbox

Common and Classification Name: Electroencephalograph

Classification Regulation: 21 CFR §882.1400

Product Code: GWQ

Classification Panel: Neurology

<i>Substantially Equivalent Devices:</i>	<i>New Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
	XLTEK EMU40EX EEG Headbox	K053386	XLTEK / XLTEK EMU40 EEG Headbox

Device Description: The Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) EMU40EX System is a powerful and flexible EEG recording system. The EMU40EX System consists of a patient electrode set, EMU40EX EEG Headbox, and the Natus Base Unit.

The EMU40EX System is designed to work with an XLTEK host computer system running the Natus Database and Natus NeuroWorks® data review and analysis software.

The EMU40EX EEG Headbox can be connected to the Natus Base Unit with a cable, or can connect wirelessly through a secure Bluetooth link.

510(k) Summary

Intended Use:

The XLTEK EMU40EX EEG Headbox is an electroencephalograph that works in conjunction with XLTEK NeuroWorks® software.

The XLTEK EMU40EX EEG Headbox is used to acquire, digitize, store and transmit physiological signals (such as EEG, pulse and oximetry signals) for EEG studies in research and clinical environments.

The XLTEK EMU40EX EEG Headbox requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgement in using this information.

Technology Comparison:

The XLTEK EMU40EX EEG Headbox employs the same technological characteristics as the predicate device.

<i>ECG System Characteristic</i>	<i>XLTEK EMU40 EEG Headbox (K053386)</i>	<i>XLTEK EMU40EX EEG Headbox (Proposed Device)</i>
<i>Intended Use</i>	The XLTEK EMU40 EEG Headbox is an electroencephalograph that works in conjunction with XLTEK NeuroWorks software. The XLTEK EMU40EX EEG Headbox is used to acquire, digitize, store and transmit physiological signals (such as EEG, pulse and oximetry signals) for EEG studies in research and clinical environments. The XLTEK EMU40EX EEG Headbox requires competent user input, and its output must be reviewed and interpreted by trained medical professionals who will exercise professional judgement in using this information.	Same
<i>Referential Channels</i>	40	Same
<i>DC Channels</i>	Four (4) isolated	Same
<i>Electrode Connections (including common input)</i>	Touch-proof	Same
<i>Oximeter Connection</i>	Yes	Same
<i>Photic Stimulator Connection</i>	Yes	Same
<i>Patient Event Button</i>	Yes	Same

510(k) Summary

Technology Comparison (continued):

<i>ECG System Characteristic</i>	<i>XLTEK EMU40 EEG Headbox (K053386)</i>	<i>XLTEK EMU40EX EEG Headbox (Proposed Device)</i>
<i>Batteries</i>	Two (2) AAA Rechargeable	Same
<i>Compatible with Rechargeable External Battery Pack</i>	Yes	Same
<i>Front Panel Base Unit Controls</i>	LCD Display Four (4) buttons	Touchscreen LCD display.

Summary of Performance Testing:

Software

The XLTEK EMU40EX EEG Headbox firmware was designed and developed according to a robust software development process, and was rigorously verified and validated. Firmware information is provided in accordance with internal firmware 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.*
- *IEC 62304: 2006, Medical device software – Software life cycle processes*

Results indicate that the XLTEK EMU40EX EEG Headbox firmware passed verification and validation, complies with its predetermined firmware specifications, the applicable guidance documents, and the applicable standards.

Electrical Safety

The XLTEK EMU40EX EEG Headbox was verified for performance in accordance with the following standard:

- *IEC 60601-1: 2005, Am1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Results indicate that the XLTEK EMU40EX EEG Headbox passed verification, and complies with the applicable standards.

510(k) Summary

Electromagnetic Compatibility

The XLTEK EMU40EX EEG Headbox was verified for performance in accordance with the following standard:

- *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.*

Results indicate that the XLTEK EMU40EX EEG Headbox passed verification, and complies with the applicable standards.

Performance Testing – Bench

The XLTEK EMU40EX EEG Headbox was verified and validated for performance in accordance with product requirements including:

- Signal quality.
- Functionality.
- User interface.

and the applicable clauses of the following standards:

- *IEC 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.*
- *IEC 60601-2-26: 2012, Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *ISO 80601-2-61: 2011, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*

Results indicate that the XLTEK EMU40EX EEG Headbox passed verification and validation, and complies with the product requirements 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 XLTEK EMU40EX EEG Headbox. The results of these activities demonstrate that the XLTEK EMU40EX EEG Headbox is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the XLTEK EMU40EX EEG Headbox is considered substantially equivalent to the predicate device.