DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 4, 2016

Natus Medical Incorporated Dba Excel-tech Ltd. (xltek)
Sanjay Mehta
Senior Manager, Quality Assurance & Regulatory Affairs
2568 Bristol Circle
Oakville, CA

Re: K162595
Trade/Device Name: Trex_HD
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: September 14, 2016
Received: September 15, 2016

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.

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 -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162595

Device Name
Trex_HD

Indications for Use *(Describe)*
The Trex_HD is an electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex_HD amplifier is designed to be used with Natus NeuroWorks™ or Natus SleepWorks™ software.

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
PRAStaff@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:	14 September 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:	Trex_HD
Common and Classification Name:	Electroencephalograph
Classification Regulation:	21 CFR §882.1400
Product Code:	GWQ, OLV

Substantially Equivalent Devices:	*New Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Trex_HD	K131266	XLTEK / Trex_HD

Device Description: The Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) Trex_HD is a complete data acquisition system that incorporates built-in amplifiers, A/D converters, digital signal processors, and storage devices.

The Trex_HD incorporates the following patient inputs:

- 24 referential inputs;
- DC inputs;
- Differential inputs;
- Pulse oximeter/photic input; and
- Patient event switch input.

510(k) Summary

Device Description: (continued)

The Trex_HD also incorporates the following connection to a XLTEK DT computer running NeuroWorks or SleepWorks software applications:

- USB connection;
- External battery pack connection; and
- Bluetooth (BT) wireless connection.

The Trex_HD is powered by two (2) AA batteries, or may utilize an external battery pack for longer studies.

Intended Use:

The Trex_HD is an electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex_HD amplifier is designed to be used with Natus NeuroWorks™ or Natus SleepWorks™ software.

Technology Comparison:

The XLTEK Trex_HD employs the same technological characteristics as the predicate device.

ECG System Characteristic	***XLTEK Trex_HD Predicate Device (K131266)***	***XLTEK Trex_HD (Proposed Device)***
Intended Use	The Trex_HD is an electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex_HD amplifier is designed to be used with Natus NeuroWorks™ or Natus SleepWorks™ software.	Same
24 Referential Inputs	± 10	Same
Four (4) Differential Inputs	± 20	Same
Electrode Connections (including common input)	Safety Touch	Same
Four (4) Non-isolated DC Inputs	± 5 V	Same
Oximeter/Photic Stimulator Connection	Yes (either/or)	Same
Patient Event Button	Yes	Same
Batteries	Two (2) AA	Same

510(k) Summary

ECG System Characteristic	*XLTEK Trex_HD Predicate Device (K131266)*	*XLTEK Trex_HD (Proposed Device)*
Compatible with Rechargeable External Battery Pack	No	Yes
Bluetooth Use	Transmission of time stamp from video recorder to amplifier to allow time synchronization between video images recorded in a separate camcorder and the physiological signals recorded on the Trex_HD amplifer.	Transmission of streaming EEG data over Bluetooth from Trex_HD to acquisition PC during the study to allow for monitoring of study data in real time.

Summary of Performance Testing:

Software

The XLTEK Trex_HD 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 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 Trex_HD firmware complies with its predetermined specifications, the applicable guidance documents, and the applicable standards.

Electrical Safety

The XLTEK Trex_HD 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.*
- *IEC 60601-1-11: 2011, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

Results indicate that the XLTEK Trex_HD complies with the applicable standards.

510(k) Summary

Electromagnetic Compatibility

The XLTEK Trex_HD 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 Trex_HD complies with the applicable standards.

Performance Testing – Bench

The XLTEK Trex_HD was verified for performance in accordance with internal requirements 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 Trex_HD 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 XLTEK Trex_HD. The results of these activities demonstrate that the XLTEK Trex_HD is as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the XLTEK Trex_HD is considered substantially equivalent to the predicate devices.