February 22, 2018

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

Re: K180181
Trade/Device Name: Natus Quantum
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV, GYC
Dated: January 22, 2018
Received: January 23, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos Peña, Ph.D.
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)*
K180181

Device Name
Natus Quantum

Indications for Use *(Describe)*
The Natus Quantum Amplifier is intended to be used as an electroencephalograph: to acquire, display, store and archive electrophysiological signals. The amplifier should be used in conjunction with Natus NeuroWorks™/SleepWorks™ software to acquire scalp and intracranial electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals. The amplifier is designed to facilitate functional mapping using a Digital Switch Matrix. The Digital Switch Matrix portion of the headbox is a combination of hardware relays and software controls allowing the user (physician or technologist) to switch electrode pairs between the EEG recording amplifier and the external cortical stimulator for stimulus delivery.

The Natus Quantum Amplifier is intended to be used by trained medical professionals, and is designed for use in clinical environments such as hospital rooms, epilepsy monitoring units, intensive care units, and operating rooms. It can be used with patients of all ages, but is not designed for fetal use.

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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Submission Date:	22 January 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 Director, Quality and Regulatory Affairs Phone: +1 (905) 287-5055 Fax: +1 (905) 829-5304 Email: sanjay.mehta@natus.com
Manufacturing Site:	Ducommun LaBarge Technologies 2222 East Pensar Drive Appleton, WI 54911 USA
Trade Name:	Natus Quantum
Common and Classification Name:	Full-Montage Standard Electroencephalograph
Classification Regulation:	21 CFR §882.1400
Product Code:	GWQ, OLV, GYC

Substantially Equivalent Devices:

New Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Natus Quantum	K143440	Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle Oakville, Ontario, L6H 5S1, Canada / Natus Quantum

Device Description:

The Natus Quantum Amplifier is the front end hardware of an electroencephalograph, and consists of amplifier circuitry, A/D Converters, Digital Signal Processing, digital switch matrix, LCD touch screen interface as well as TCP/IP & USB connection options of PC communication.

The Natus Quantum Amplifier can record either in Tethered mode or in Ambulatory Mode. In Ambulatory Mode, data is stored in the Quantum Breakout's internal memory and automatically uploaded to the main study folder when the Quantum Breakout is reconnected to the Natus Base unit.

The amplifier is designed to facilitate functional mapping using a Digital Switch Matrix. The Digital Switch Matrix portion of the headbox is a combination of hardware relays and software controls allowing the user (physician or technologist) to switch electrode pairs between the EEG recording amplifier and the external cortical stimulator for stimulus delivery by an external cortical stimulator.

Intended Use:

The Natus Quantum Amplifier is intended to be used as an electroencephalograph: to acquire, display, store and archive electrophysiological signals. The amplifier should be used in conjunction with Natus NeuroWorks™/SleepWorks™ software to acquire scalp and intracranial electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals. The amplifier is designed to facilitate functional mapping using a Digital Switch Matrix. The Digital Switch Matrix portion of the headbox is a combination of hardware relays and software controls allowing the user (physician or technologist) to switch electrode pairs between the EEG recording amplifier and the external cortical stimulator for stimulus delivery.

The Natus Quantum Amplifier is intended to be used by trained medical professionals, and is designed for use in clinical environments such as hospital rooms, epilepsy monitoring units, intensive care units, and operating rooms. It can be used with patients of all ages, but is not designed for fetal use.

The subject and predicate devices have the same Indications for Use and the same intended use.

Technology Comparison:

The Natus Quantum employs the same technological characteristics as the predicate device.

Specification	Predicate Device Natus Quantum (K143440)	Subject Device Natus Quantum (Modified)
	Analog Specifications EEG Channels	
EEG Channels	64-256	64-256
Reference Channels	Dedicated separate reference and ground	Dedicated separate reference and ground
Input Impedance	>1000 MOhm	>1000 MOhm
Input Noise	< 1.5uV pk to pk @ .1….100Hz bandwidth (<0.53uV rms@1….100Hz bandwidth)	< 2.0uV pk to pk @ .1….100Hz bandwidth (<0.53uV rms@1….100Hz bandwidth)
Input signal range	20mV pk-to-pk	20mV pk-to-pk
Maximum Operational DC input voltage electrode offset	±300mV	±300mV
Input Bias Current	<1nA	<1nA
Common mode Rejection Ratio	>110dB@60Hz	>106dB@60Hz
	Digital Specifications	
Sampling Frequency	256, 512, 1024, 2048, 4096, 8192, 16384 Hz	256, 512, 1024, 2048, 4096, 8192, 16384 Hz
Sampling Resolution - EEG channels	24 bits	24 bits
Sampling Quantization – EEG channels	305nV	305nV
Storage Resolution – EEG Channels	16 bits	16 bits
	Quantum Breakout Box Feature	
Referential Channels	128 referential channels per breakout, 2 breakouts cascade-able up to 256 channels	128 referential channels per breakout, 2 breakouts cascade-able up to 256 channels
Differential channels	Up to 8 configurable differential channels per 128 channel breakout (2 inputs per channel)	Up to 8 configurable differential channels per 128 channel breakout (2 inputs per channel)

Summary of Performance Testing:

Software

The Natus Quantum 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, Am1: 2015, Medical device software – Software life cycle processes*

Results indicate that the Natus Quantum firmware complies with its predetermined specifications, the applicable guidance documents, and the applicable standards.

Electrical Safety

The Natus Quantum 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 Natus Quantum complies with the applicable standards.

Electromagnetic Compatibility

The Natus Quantum was verified for performance in accordance with the following standard:

- IEC 60601-1-2 Edition 4.0 2014-02, *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 Natus Quantum complies with the applicable standards.

Performance Testing – Bench

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

- *IEC 60601-1-6 Edition 3.1 2013-10, 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, Am1: 2014, 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 Natus Quantum 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 Natus Quantum. The results of these activities demonstrate that the Natus Quantum is as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the Natus Quantum is considered substantially equivalent to the predicate devices.