DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 20, 2015

Natus Medical Incorporated
DBA Excel-Tech Ltd. (Xltek)
Sanjay Mehta
Quality and Regulatory Affairs Manager
2560 Bristol Circle
Oakville, Ontario, Canada, L6H5S1

Re: K143440
Trade/Device Name: Natus Quantum Amplifier
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV, GYC
Dated: March 18, 2015
Received: March 19, 2015

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" (21CFR 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 yours,

Felipe Aguel -S

for Carlos Peña, PhD, MS
Division 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)*
K143440

Device Name
Natus Quantum Amplifier

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.

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510K Summary

Date: April 15, 2015

Submitted by: Natus Medical Incorporated
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Natus Medical Incorporated
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Proprietary Name: Natus Quantum

Common Name: Electroencephalograph

Regulation Number : 21CFR 882.1400

Classification Name: Full-montage standard electroencephalograph

Product code: GWQ, OLV

Device Class: II

Predicate Device: EMU128 (K040360); Neurolink IP 256 (K100683)

Description:

1. Overview: Natus Quantum Amplifier

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.

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2. Operating Principle of the Quantum Amplifier

The Natus Quantum amplifier is comprised of a base unit and several breakout boxes. It is part of a system that is made up of a personal computer, a photic stimulator, an isolation transformer, video and audio equipment, networking equipment, and mechanical supports. The amplifier also contains an internal switch matrix to allow for a connection to an external cortical stimulator.

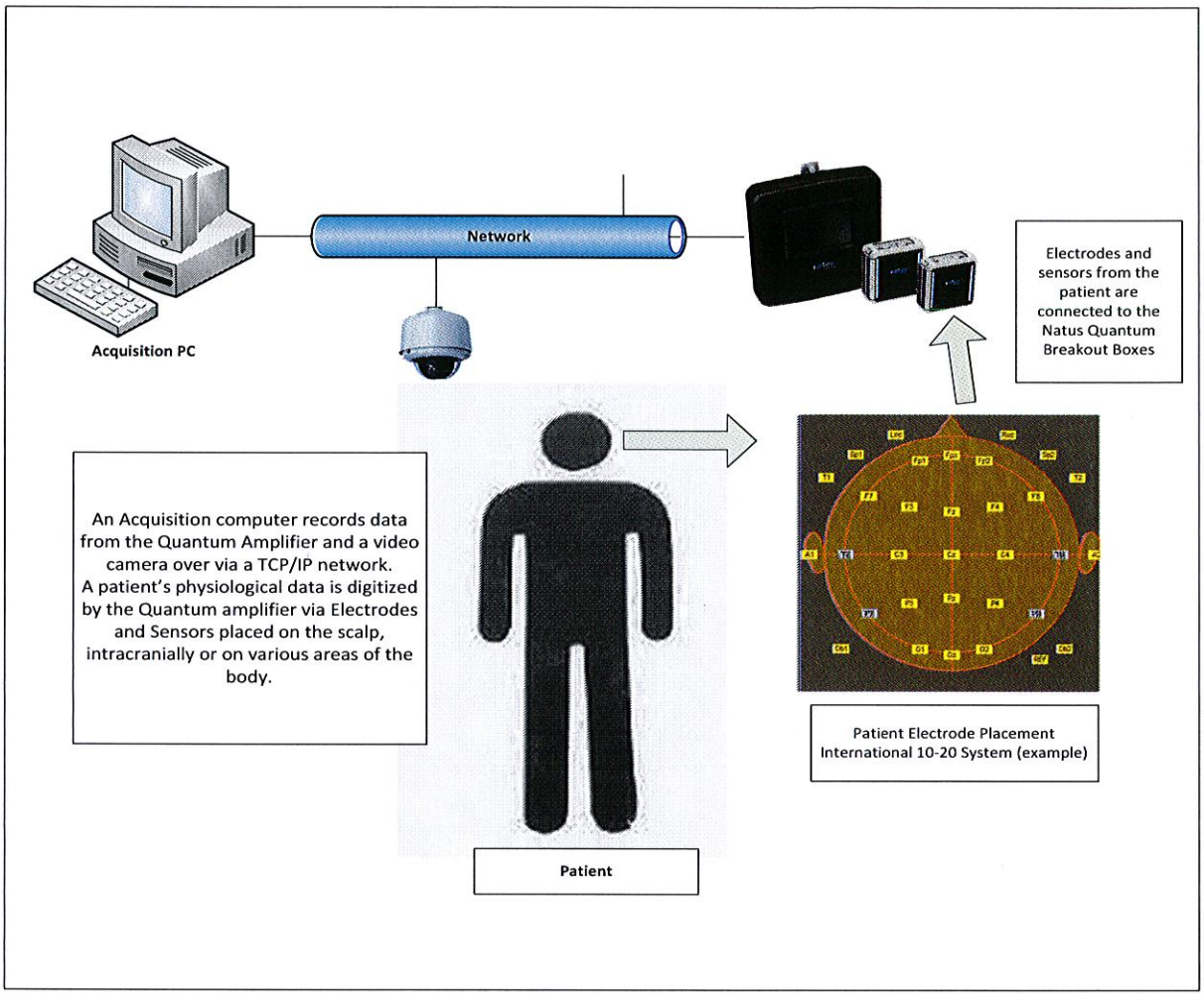
EEG and other physiological signals, from scalp electrodes, grid or needle electrodes, and other accessories such as pulse oximeters can be acquired by the Natus Quantum amplifier. These signals are digitized and transmitted to the personal computer running the ***Natus*** NeuroWorks software. The signals are displayed on the personal computer and can be recorded to the computer's local storage or to remote networked storage for later review.

Quantum features include

- 128 referential channels (cascade-able up to 256).
- 16 referential inputs per 128 can be configured as 8 differential inputs
- 16 DC channels,
- Pulse Oximeter including SpO2, Pulse Rate and Pleth signals
- Digital Trigger Input
- Ability to initiate an impedance test, change the threshold, and view the results in the patient room
- Digital Switch Matrix
- A small and lightweight wearable breakout box
- TCP/IP and USB connectivity
- Patient-event switch interface on both the breakout box and base units
- Photic stimulator interface for EEG applications
- Modular pouch for belt or backpack harness

System Setup Overview

The Natus Quantum amplifier connects to the Natus NeuroWorks (K090019) & Natus SleepWorks (K090277) software for the acquisition storage, analysis, and review of Electroencephalographic & Polysomnographic data in conjunction with synchronized digital video. The system overview is as follows.



Device-patient interaction Accessories List:

The table below lists all accessories to the subject device. Accessories (1) to (9) enter in contact with the patient. These sensors guarantees acquisition of the physiological signals and passively transfer them to the head box. Characteristics of the sensors vary and are described (cleared) under their respective 510K submissions (see table).

	Description	Body contact location	Device connection
1	Reusable gold disk electrode (K982053)	Scalp (according to 10-20 & 10-10 system)	Referential and differential inputs (labeled numerically)
2	Single Use Intracranial Grids, Strips and Depth Electrodes. (K082474)	Intracranial recordings	Referential and differential inputs (labeled numerically)
3	Body position sensor (K923033)	Thorax	DC input
4	Xactrace (K043132)	Respiratory belts	Differential input

		Thorax/Abdomen	
6	Thermistor (K922112)	Nasal/Oral	DC input
7	Pulse Oximeter Sensor (K092101)	Finger	Channel labeled "oximeter/photic"
8	Snoring microphone (K941759)	Nasion/cheek/chin or side of the neck	DC input
9	Airflow Pressure Sensor (K922112)	Nasal	DC input
10	Photic Stimulator (K991903)	None	Channel labeled "oximeter/photic"
11	Cortical Stimulator (K072964)	Intracranial contacts	Amplifier Digital Switch Matrix input port.

Indications for Use

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Comparison to Predicate Device

Specification	**Predicate Device** EMU128S (K040360)	**Predicate Device** NeuroLink IP (K100683)	**Subject Device** Natus Quantum
Manufacturer	Excel-Tech Ltd.(Xltek)	Excel-Tech Ltd.(Xltek)	Excel-Tech Ltd.(Xltek)
Technological Characteristics			
Analog Specifications EEG Channels			
EEG Channels	128	64-256	64-256
Reference Channels	Dedicated separate reference and ground	Dedicated separate reference and ground	Dedicated separate reference and ground
Input Impedance	>47 MOhms	> 100 MOhms	>1000 MOhm
Input Noise	< 2uV pk to pk @ full bandwidth	< 1uV rms @ 1....70Hz bandwidth	< 1.5uV pk to pk @ .1....100Hz bandwidth (<0.53uV rms@1....100Hz bandwidth)

Maximum Operational DC input voltage electrode offset	±300V	±300V	±300V
Input Bias Current	< 20pA	< 1 nA	<1nA
Common mode Rejection Ratio	>110dB@60Hz	>40dB@60Hz	>110dB@60Hz
Digital Specifications			
Sampling Frequency	256, 512, 1024, 2048	256, 512, 1024 Hz	256, 512, 1024, 2048, 4096, 8192, 16384 Hz
Sampling Resolution - EEG channels	22 bits	16 bits	24 bits
Sampling Quantization – EEG channels	310 nV	179 nV	305nV
Storage Resolution – EEG Channels	16 bits	16 bits	16 bits

For a detailed discussion covering any differences between devices and why they do not raised any new safety or effectiveness issues, the reviewer is referred to VOL_007_Substantial Equivalence discussion.

Brief Summary of Performance Tests

Non-clinical:

Testing of the Natus Quantum was performed in compliance with Natus Corporation design control process. The validation was carried out as part of verification. Testing included:

Test	Results
Signal Quality Verification Test	Pass
Functionality Verification Test	Pass

It was found that the Natus Quantum system meets the design specification and performs as specified.

The device is in compliance with the following industrial standards

Safety Standard of Compliance and normative references

Standards	Title
CAN /CSA-C22.2 No. 60601-1: 08(R2013) + C2:2011 ANSI/AAMI ES60601-1:2005/(R)2012 + C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1:2005 + C1:2006 and C2:2007, Third Edition CENELEC EN 60601-1:2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010, Edition 3.0	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366:2007, Edition 1.0	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-26:2012, Edition 3 CENELEC EN 60601-2-26L2003, Edition 2	Medical electrical equipment – Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 80601-2-61:2011, Edition 1	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

EMC Standard of Compliance and normative references

Standards	Title
IEC 60601-1-2:2007, Edition 3.0	Medical electrical equipment – Part 1-2: General requirements for safety – collateral standard: electromagnetic compatibility – requirements and tests
IEC 61000-4-2:2008, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test

IEC 61000-4-3 ed 3.0 with A1:2007+A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6 ed 2.0 with A1:2004 + A2:2006	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:2014, ed 4.0	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2013, ed 3.0	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11 ed 5.0 with A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

Quality System Compliance:

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes.
- SOR/98-282 Canadian Medical Device Regulations
- 21 CFR Part 820 US Food and Drug Administration's Quality System Regulation
- 93/42/EEG European Medical Device Directives
- ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices
- EN 980:2008 Medical Devices - Symbols for Use of labeling of medical device
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- ISO 15223-1:2012,Medical Devices - Symbols to be Used With Medical Device Labels, Labeling, and Information to be Supplied - Part 1: General requirements
- IEC 62304:2006 Medical device software - Software life-cycle processes

Conclusions

The substantial equivalence of the Natus Quantum with EMU128S and Neurolink IP products was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Natus Quantum is similar to that of the predicate device XLTEK-EMU128S and Neurolink IP. Verification and Validation was performed to ensure no new questions of safety or effectiveness are raised.