June 14, 2018

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

Re: K180290
Trade/Device Name: Natus Brain Monitor, Embla Dx series
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: March 15, 2018
Received: March 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 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,

Jay R. Gupta -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180290

Device Name
Natus Brain Monitor, Embla Dx series

Indications for Use *(Describe)*
The Natus Brain Monitor 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 Natus Brain Monitor 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: May 24, 2018

Submitted by: Natus Medical Incorporated
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E-mail: sanjay.mehta@natus.com

Proprietary Name: Natus Brain Monitor, Embla Dx series (includes models Embla NDx & Embla SDx)

Common Name: Electroencephalograph

Regulation Number : 21CFR 882.1400

Classification Name: Standard Polysomnograph with Electroencephalograph

Product code: GWQ, OLV

Device Class: II

Predicate Device: Natus Quantum (K143440); N7000 System (K111742), Comet-Plus (K172711)

Description:

1. Overview: Natus Brain Monitor

The Natus Brain Monitor family of amplifiers are 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 electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals.
The Natus Brain Monitor family of amplifiers are intended to be used by trained medical professionals, and are designed for use in clinical environments such as hospital rooms, clinics, 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.

2. Operating Principle of the Quantum Amplifier

The Natus Brain Monitor (Natus Embla NDx, Natus Embla SDx) are comprised of a base unit and a breakout box. It is part of a system that is made up of a personal computer, software, a photic stimulator, an isolation transformer, video and audio equipment, networking equipment, and mechanical supports.
EEG and other physiological signals from electrodes placed on the head and body as well as other accessories such as pulse oximeters, respiratory effort and airflow sensors can be acquired by the amplifiers.` The amplifiers include sensor inputs for respiratory effort and airflow as well as snoring. The amplifiers include an integrated pressure sensor and pulse oximeter module. These signals are digitized and transmitted to the personal computer running the Natus NeuroWorks/SleepWorks 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.

2.1. Brain Monitor

2.2. Embla NDx

2.3. Embla SDx

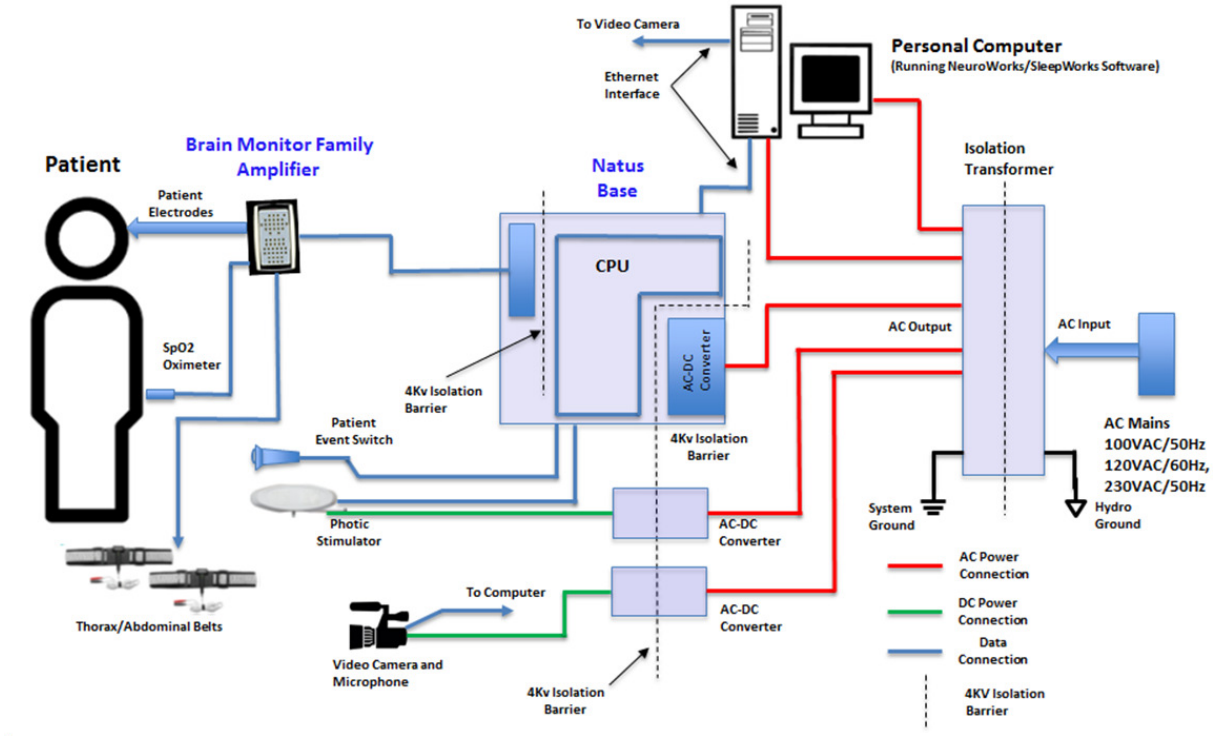
The Natus Brain Monitor and Natus Embla NDx are identical devices. The only difference is the brand name/label on the front face of the breakout box. The Natus Embla SDx is a limited functionality version of the Natus Embla NDx with fewer inputs and some features turned off.

Natus Brain Monitor features include

- Up to 64 AC inputs (40 referential, and 24 referential/differential configurable)
- Up to 16 DC channels (12 on Natus Base unit + 4 on Brain Monitor & Embla NDx Breakouts)
- Integrated Pulse Oximeter including SpO2, Pulse Rate and Plethysmogram signals
- Ability to initiate an impedance test, change the threshold, and view the results in the patient room
- Digital Trigger Input
- A small and lightweight 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 (excluding Embla SDx).
- Holster for cart mounting
- Pouch for extended EEG studies

System Setup Overview

The Natus Brain Moniotr family of amplifiers 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 (7) 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/Usage
1	Reusable gold disk electrode (K982053)	Scalp (according to 10-20 & 10-10 system)	Referential and differential inputs **Usage:** To record the EEG/EOG/EMG surface potentials.
2	Single Use Intracranial Grids, Strips and Depth Electrodes (K082474)	Intracranial recordings	Referential and differential inputs (labeled numerically) **Usage:** For the recording, monitoring and stimulation of electrical signals.
3	Xactrace (K043132)	Respiratory belts Thorax/Abdomen	Sensor input **Usage:** to measure respiratory effort signals
4	Thermistor (K922112)	Nasal/Oral	DC input **Usage:** to monitor breathing frequency
5	Pulse Oximeter Sensor (K092101)	Finger	Channel labeled "oximeter/photic" **Usage:** non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused
6	Snoring microphone (K941759)	Nasion/cheek/chin or side of the neck	DC input **Usage:** To monitor breathing frequency
7	Cannula (K922112)	Nasal/Oral	Pressure input **Usage:** To monitor breathing frequency
8	Body position Pod (K122516)	Thorax	Sensor input **Usage:** Position or movement recording
9	Photic Stimulator (K991903)	None	Photic input (base unit) **Usage:** For photic activation of the EEG in visual evoked potential
10	Holster/Mounting arm/Roll Stand (510K –Not applicable)	None Back/shoulder straps	None **Usage:** Used to attach Quantum breakout boxes in as a backpack to keep them out of the way of the patient.
11	Pouch (510K# Not Applicable)	None	None **Usage:** To keep the breakout and electrodes protected and easy to move.
12	XLTEK Trolley and Carts (510K# Not Applicable)	None	None **Usage:** Cart optimized for sitting users on which the recording computer resides.

Indications for Use

The Natus Brain Monitor 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 Natus Brain Monitor 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.

Comparison to Predicate Device

Specification	**Predicate Device** Natus Quantum (K143440)	**Predicate Device** N7000 System (K111742)	***Predicate Device*** Comet-PLUS® (K172711)	**Subject Device** Natus Brain Monitor Model #1: Natus Brain Monitor Model #2: Natus Embla NDx Model #3: Natus Embla SDx
Manufacturer	Natus Medical Incorporated Dba. Excel Tech Ltd (Xltek)	Embla Systems a division of Natus Medical Incorporated	Natus Medical Incorporated Dba. Excel Tech Ltd (Xltek)	Natus Medical Incorporated Dba. Excel Tech Ltd (Xltek)
Referential Channels	256 128 per Breakout	32	*32*	40 (programmable to up to 64) 16 (Embla SDx Model)
Bipolar Channels	16 8 per Breakout	8	*8*	12 4 (Embla SDx Model)
DC inputs	16 (+/-5Vdc)	8 (+/-5Vdc)	*8 (+/-2.5Vdc)*	16 (+/-5Vdc) 8 (+/-5Vdc) – For Embla SDx model
SpO2	SpO2, Pulse Rate, Plethmogram	SpO2, Pulse Rate, Plethmogram	*SpO2 Pulse Rate, Plethsmogram, PPG*	*SpO2 Pulse Rate, Plethsmogram, PPG*
Body Position	Uses a universal sensor via DC input	Integrated Proprietary	Uses a universal sensor via DC input	Integrated proprietary
Resolution	24 bit (16 bit stored)	22 bit	*16 bit*	24 bit (16 bit stored)
EEG Channels	64-256	40	32	64 20 (Embla SDx)
Reference Channels	Dedicated separate reference and ground	Dedicated ground	Dedicated separate reference and ground	Dedicated separate reference and ground

Input Impedance	>1000 MOhm	>20MΩ	≥20 MΩ	>1000 MOhm
Input Noise	< 1.5uV pk to pk @ .1….100Hz bandwidth (<0.53uV rms@1….100Hz bandwidth)	Referential channels: Noise levels when sampling at 200Hz is less than 1µVrms Noise levels when sampling at 200Hz is less than 2µVrms	*<2uV pk to pk*	≤ 2 uV pk-to-pk (0.1Hz to 100 Hz),
Input signal range	20mV pk-to-pk	Vin = ±350mV on bipolar channels, Vin = ±75mV dynamic range on referential channels	*4 mV peak to peak full-scale*	20mV pk-to-pk, +/- 0.3VDC
Input Bias Current	<1nA	< 5nA	<4 nA	<1nA
Maximum Operational DC input voltage electrode offset	±300mV	±1V	*±500 mV*	±300mV
Common mode Rejection Ratio	>110dB@60Hz	>80dB	*>80 dB (signal ref), > 100 dB (earth ref)*	>106db@60Hz
Sampling Frequency	256, 512, 1024, 2048, 4096, 8192, 16384 Hz	64, 128, 256, 512Hz	*200 Hz, 256 Hz, 400 Hz, 512 Hz, 800 Hz*	256, 512, 1024, 2048, 4096 256, 512Hz (Embla SDx)
Sampling Resolution - EEG channels	24 bits	22 bits	16 bits	24 bits
Sampling Quantization – EEG channels	305nV	N/A	0.06 µV/bit	305nV
Storage Resolution –	16 bits	16 bits	16 bits	16 bits
Impedance Check	<2.5, <5, <10, <25, <50kOhms	0 to 100kΩ	<2, <5, <10, <20 kΩ	2.5kΩ, 5kΩ, 10kΩ, 25kΩ

Brief Summary of Performance Testing

Electrical Safety

The Natus Brain Monitor 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 Brain Monitor complies with the applicable standards.

Electromagnetic Compatibility

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

- *IEC 60601-1-2Edition4.0 : 2014-02, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*
- *IEC 60601-2-26: 2012, Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.*

Results indicate that the Natus Brain Monitor complies with the applicable standards.

Performance Testing – Bench

The Natus Brain Monitor was verified for EEG hardware 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*

The bench testing was performed to confirm

- EEG hardware Signal Quality such as leakage, noise, signal range, offset, CMRR, input impedance and cross talk.
- Functional testing of the Amplifier with NeuroWorks/SleepWorks software
- Device performance at extreme Environmental and storage limits
- Functional testing of the Amplifier with various accessory such as various type of Electrodes, Xactace belts, Thermistor ,Photic stimulators etc.

Results indicate that the Natus Brain Monitor complies with its predetermined specifications and the applicable standards.

Conclusions

The substantial equivalence of the Natus Brain Monitor with Natus Quantum, N7000 and Comet-Plus products was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Natus Brain Monitor is similar to that of the predicate device(s). Verification and Validation were performed to ensure no new questions of safety or effectiveness are raised. The results of these activities demonstrate that the Natus Brain Monitor is as safe, as effective, and performs as well as or better than the predicate devices.