December 19, 2017

Natus Neurology Incorporated
Shane Sawall
Manager, Regulatory Affairs
3150 Pleasant View Road
Middleteon, Wisconsin 53562

Re: K172743
Trade/Device Name: Natus VikingQuest
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, JXE, GWF, OLT, GWJ, GWE, GZP
Dated: September 7, 2017
Received: September 12, 2017

Dear Mr. Sawall:

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 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)*
K172743

Device Name
Natus VikingQuest

Indications for Use *(Describe)*
The Natus VikingQuest is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP) , Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Natus VikingQuest may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The VikingQuest is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Natus VikingQuest is intended to be used by a qualified healthcare provider.

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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510(k) Summary

Submission Date:	07 September 2017
Submitter:	Natus Neurology Incorporated 3150 Pleasant View Road Middleton, WI 53562 USA
Submitter and Application Correspondent	Mr. Shane T. Sawall Phone: +1 (608) 829-8673 Fax: +1 (608) 829-8771 Email: shane.sawall@natus.com
Manufacturing Site:	Natus Neurology Incorporated 3150 Pleasant View Road Middleton, WI 53562 USA
Trade Name:	Natus VikingQuest
Common and Classification Name:	Diagnostic electromyograph, and evoked response stimulator
Classification Regulation:	21 CFR §890.1375, 21 CFR §882.1550, 21 CFR §882.1870, 21 CFR §882.1400, 21 CFR §882.1900, 21 CFR §882.1890, 21 CFR §882.1880
Product Code:	IKN, JXE, GWF, OLT, GWJ, GWE, GZP

Substantially Equivalent Devices:	*New Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Natus VikingQuest	K130346 (Primary predicate)	Natus Neurology Incorporated Synergy Focus Desktop Version; Synergy Focus Laptop Version
		K120979 (Reference predicate)	Carefusion 209, Inc. (now Natus Neurology Incorporated) / Carefusion Nicholet EDX

510(k) Summary

Device Description: The Natus VikingQuest is designed for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular systems. The system is designed to perform nerve conduction studies (NCS), needle electromyography (EMG) testing, evoked potential (EP) testing, and intra-operative monitoring (IOM). VikingQuest provides a variety of tests spanning the various modalities. There are two configurations, portable and cart-based.

Intended Use: The Natus VikingQuest is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), Evoked Potentials (EP), Autonomic Responses and Intra-Operative Monitoring including Electroencephalography (EEG).

Evoked Potential (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), Somatosensory Evoked Potentials (SEP) , Electroretinography (ERG), Electrooculography (EOG), P300, Motor Evoked Potentials (MEP) and Contingent Negative Variation (CNV). The Natus VikingQuest may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The VikingQuest is used to detect the physiologic function of the nervous system, for the location of neural structures during surgery, and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the nerve; Electromyography measures the electrical activity of the muscle and Evoked Potentials measure electrical activity from the Central Nervous System.

The Natus VikingQuest is intended to be used by a qualified healthcare provider.

510(k) Summary

Technology Comparison:

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

EMG System Characteristic	***Natus Neurology Synergy Focus (K130346)***	***Natus Neurology VikingQuest (Proposed Device)***
Modalities	Nerve Conduction (NCS) Electromyography (EMG) Evoked Potential (EP) Other Tests Intra-operative Monitoring (IOM)	Same
Software Features	Electrical Stimulus Automation Automatic Report Narrative Generation	Same
Number of Amplifier Signal Recording Channels	1 to 3	1 to 4
Stimulator Options	Constant Current	Selectable: Constant Current or Constant Voltage
Number of Stimulators	1	Same
Bi-phasic Stimulator	Yes	No
Auditory Stimulation Types (Click, pip and burst)	Yes	Same
Visual Stimulation	Yes	Same

Summary of Performance Testing:

Biocompatibility

The Natus VikingQuest has no patient contact materials, and therefore this section does not apply to them.

Accessories for use with the Natus VikingQuest have patient contact materials and are made from medical grade biocompatible materials.

The appropriate component materials for these accessories were previously verified to be biocompatible in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicate that the appropriate component materials comply with the standard.

510(k) Summary

Software

The Natus VikingQuest software was designed and developed according to a robust software development process, and was rigorously verified and validated consistent with 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+A1:2015, Medical device software – Software life cycle processes*

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

Electrical Safety

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

- *AAMI/ANSI ES60601-1: 2005/(R)2012, A1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Results indicate that the Natus VikingQuest complies with the applicable standards.

Electromagnetic Compatibility

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

- *IEC 60601-1-2: 2014, 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 VikingQuest complies with the applicable standards.

510(k) Summary

Performance Testing – Bench

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

- *IEC 60601-1-6: 2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
- *IEC 60601-2-40: 2016, Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment.*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*

Results indicate that the Natus VikingQuest 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 VikingQuest. The results of these activities demonstrate that the Natus VikingQuest is as safe, as effective, and performs as well as or better than the predicate devices.

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