November 3, 2017

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

Re: K172711
Trade/Device Name: Comet-PLUS
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, GWQ
Dated: September 7, 2017
Received: September 8, 2017

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 (DICE) 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 (DICE) 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 -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)*
K172711

Device Name
Comet-PLUS®

Indications for Use *(Describe)*
The Comet-PLUS® is designed for use in the recording of routine EEG, overnight sleep/EEG (PSG, Polysomnography), and other neurophysiological monitoring applications. This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in either electroencephalography or polysomnography.

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.

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Submission Date: 07 September 2017

Submitter:
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Manufacturing Site:
Ducommun LaBarge Technologies
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USA

Trade Name: Comet-PLUS®

Common and Classification Name: Standard Polysomnograph With Electroencephalograph

Classification Regulation: 21 CFR §882.1400

Product Code: OLV, GWQ

Substantially Equivalent Devices:

New Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
XLTEK / Comet-PLUS®	K021807	Grass-Telefactor Product Group, Astro-Med, Inc. / Grass-Telefactor AS40 Amplifier System

Device Description: The Natus Medical Incorporated (Natus) DBA Excel-Tech Ltd. (XLTEK) Comet-PLUS® (also known as the AS40-PLUS Amplifier System) is designed specifically for the EEG and PSG monitoring lab.

The different configurations of the Comet-PLUS feature the AS40-PLUS Amplifier with electroencephalograph (EEG) or polysomnograph (PSG) Comet-PLUS Personality Modules (headboxes) and Natus software. The Comet-PLUS Amplifier is a compact AC Amplifier with up to 57 channels for EEG and PSG recording applications.

Intended Use:

The Comet-PLUS® is designed for use in the recording of routine EEG, overnight sleep/EEG (PSG, Polysomnography), and other neurophysiological monitoring applications. This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in either electroencephalography or polysomnography.

Technology Comparison:

The Comet-PLUS employs the same technological characteristics as the predicate device.

System Characteristic	***Grass-Telefactor Product Group, Astro-Med, Inc. Grass-Telefactor AS40 Amplifier System (K021807)***	***XLTEK Comet-PLUS (Proposed Device)***
Channels	Up to 50	Up to 57
Referential AC Channels	Up to 32	Same
Bipolar AC Channels	Up to 8	Up to 8
DC Channels	Up to 8	Up to 12
Oximeter Connection	SpO_2 and heart rate (HR)	SpO_2, HR, photo-plethysmography (PPG), and plethysmogram
Photic Stimulator Connection	Yes	Same
Patient Event Button	Yes	Same
User Interface	Liquid Crystal Diode (LCD) with eight (8) push buttons on Amplifier	Same.
AC Signal Range	4 mVp-p full-scale	Same.
DC Signal Range	± 2.5 V, ± 10 V	Same.
Input Impendence	> 10 MΩ	≥ 20 MΩ

Summary of Performance Testing:

Software

The Comet-PLUS 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 Comet-PLUS firmware complies with its predetermined specifications, the applicable guidance documents, and the applicable standards.

Electrical Safety

The Comet-PLUS 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 Comet-PLUS complies with the applicable standards.

Electromagnetic Compatibility

The Comet-PLUS 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 Comet-PLUS complies with the applicable standards.

Performance Testing – Bench

The Comet-PLUS 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, 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 Comet-PLUS 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 Comet-PLUS. The results of these activities demonstrate that the Comet-PLUS is as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the Comet-PLUS is considered substantially equivalent to the predicate devices.