Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
Shane Sawall
Manager, Regulatory Affairs
2568 Bristol Circle
Oakville, Ontario L6H 5S1 CA

March 9, 2018

Re: K173690
Trade/Device Name: Grass TWin
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, GWQ
Dated: February 12, 2018
Received: February 14, 2018

Dear Shane 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 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)*
K173690

Device Name
Grass® TWin®

Indications for Use *(Describe)*
This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. It is suitable for digital acquisition, display, comparison, analysis, and archiving of EEG potentials and other rapidly changing physiological parameters.

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:*** 30 November 2017

***Submitter:***
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***Submitter and Application Correspondent***
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***Manufacturing Site:***
Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1
Canada

***Trade Name:*** Grass® TWin®

***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 / Grass TWin | K012976 | Grass-Telefactor Division, Astro-Med, Inc. / Grass-Telefactor TWin PLUS |

***Device Description:*** The Natus Medical Incorporated (Natus) DBA Excel-Tech Ltd. (XLTEK) Grass® TWin ® (Grass TWin) is a comprehensive software program intended for Electroencephalography (EEG), Polysomnography (PSG), and Long-term Epilepsy Monitoring (LTM). TWin is incredibly powerful and flexible, but also designed for easy and efficient day-to-day use. Grass TWin is a software product only, and does not include any hardware.

***Intended Use:***

This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. It is suitable for digital acquisition, display, comparison, analysis, and archiving of EEG potentials and other rapidly changing physiological parameters.

***Technology Comparison:***

The Grass TWin employs the same technological characteristics as the predicate device.

| ***System Characteristic*** | ***Grass-Telefactor Division, Astro-Med, Inc. Grass-Telefactor TWin PLUS (K012976)*** | ***XLTEK Grass TWin (Proposed Device)*** |
|---|---|---|
| *Intended Use* | This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. It is suitable for digital acquisition, display, comparison, analysis, and archiving of EEG potentials and other rapidly changing physiological parameters. | Same. |
| *Personal Computer Operating System* | Microsoft® Windows 98 or 2000 | Microsoft® Windows 7 and Windows Server 2008 |
| *Recording System Compatibility* | AURA PSG Wireless/Ambulatory Recorder<br>AURA PSG Lite Ambulatory/Wireless Sleep Screener<br>SleepTrek3 Portable Sleep Screener<br>Comet Series PSG<br>Comet Series EEG<br>AURA24 Ambulatory EEG<br>TREA Ambulatory EEG<br>Beehive Horizon for Long-Term Monitoring | AURA PSG Wireless/Ambulatory Recorder<br>AURA PSG Lite Ambulatory/Wireless Sleep Screener<br>SleepTrek3 Portable Sleep Screener<br>Comet and Comet-PLUS Series PSG<br>Comet and Comet-PLUS Series EEG<br>AURA24 Ambulatory EEG<br>TREA Ambulatory EEG<br>Beehive Horizon for Long-Term Monitoring |
| *Pulse Transit Time (PTT) Trend Option* | No | Yes |
| *Montage Editor Summation Feature* | No | Yes |

***Summary of Performance Testing:***

*Software*

The Grass TWin software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software 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.*
- *Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 Jan 05*
- *IEC 62304: 2006, Medical device software – Software life cycle processes*

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

*Performance Testing – Bench*

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

- *IEC 60601-1-6: 2010, Am1: 2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
- *IEC 62366: 2007, Am1: 2014, Medical devices – Application of usability engineering to medical devices.*

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

Therefore, the Grass TWin is considered substantially equivalent to the predicate devices.