June 15, 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: K173936
Trade/Device Name: Natus Photic Stimulator
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: May 14, 2018
Received: May 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)*
K173936

Device Name
Natus Photic Stimulator

Indications for Use *(Describe)*
The Natus Photic Stimulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.

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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Submission Date:	20 December 2017
Submitter:	Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle Oakville, Ontario, L6H 5S1 Canada
Submitter and Application Correspondent	Mr. Sanjay Mehta Phone: +1 (905) 287-5055 Fax: +1 (905) 829-5304 Email: sanjay.mehta@natus.com
Manufacturing Site:	Creation Technologies LP 6820 Creditview Road Mississauga, Ontario L5N 0A9 Canada
Trade Name:	Natus Photic Stimulator
Common and Classification Name:	Stimulator, Photic, Evoked Response
Classification Regulation:	21 CFR §882.1890
Product Code:	GWE

Substantially Equivalent Devices:

New XLTEK Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
XLTEK / Natus Photic Stimulator	K101691	Lifelines Ltd. / Lifelines Photic Stimulator

Device Description:

The Natus Medical Incorporated (Natus) DBA Excel-Tech Ltd. (XLTEK) Photic Stimulator is used by trained medical staff in a medical environment to apply photic flashes to the patient during neurophysiology studies such as electroencephalographic (EEG) studies, where it is used as an activation to test photo-sensibility related to epilepsy.

The Natus Photic Stimulator is typically used by EEG technicians in the hospital environment in fixed, mobile or portable systems, and with patients of all ages. The lamp head assembly is mounted on an arm allowing easy placement at 30 cm away from the patient's face. The arm is ergonomically designed so that the lamp can be move and rotated in the direction of the patient using a handgrip on the lamp.

Trigger pulses applied to the trigger input of the Natus Photic Stimulator generate 1 millisecond photic flashes at specific frequencies, typically in the range of 0.5 Hz to 60 Hz by a white light emitting diode (LED) lamp. The basic operating mode consists of generating a single flash per trigger pulse applied. Flash intensity has a maximum range from 22,000 lux up to 75,000 lux measured at 30 cm from the LED lamp at the position of highest intensity and 3,520 lux to 12,000 lux calculated at 75cm. The frequency and intensity of the flash is controlled by the acquisition software.

It can also be used along with evoked potential devices for stimulating visual evoked potentials.

Intended Use:

The Natus Photic Stimulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.

Technology Comparison:

The Natus Photic Stimulator employs the same technological characteristics as the predicate device.

System Characteristic	***Lifelines Ltd. Lifelines Photic Stimulator (K101691)***	***Excel-Tech Ltd. (XLTEK) Natus Photic Stimulator (Proposed Device)***
Indications for Use	The Lifelines Photic Simulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.	The Natus Photic Stimulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.
Mode of Operation	Arm-mounted photic stimulator generates flashes of white light by means of light emitting diode (LED)	Arm-mounted photic stimulator generates flashes of white light by means of LEDs.
Light Source	Single, high-intensity LED and associated optics	Surface mounted, high-intensity LED array

System Characteristic	*Lifelines Ltd. Lifelines Photic Stimulator (K101691)*	*Excel-Tech Ltd. (XLTEK) Natus Photic Stimulator (Proposed Device)*
Luminous Flux	700 lm typical, 900 lm max 13,000 lux at one (1) foot	Intensity measured at 30 cm (~ 1 foot) distance, position 12: • Minimum: 22,000 lux • Maximum: 75,000 lux Typical observed intensity is 39,900 lux.
Flash Rate	*1 to 60 Hz or single manual flash*	*0.5 to 60 Hz or single manual flash*

Summary of Performance Testing:

Electrical Safety

The Natus Photic Stimulator 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 Photic Stimulator complies with the applicable standards.

Electromagnetic Compatibility

The Natus Photic Stimulator 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.*
- *IEC 60601-2-40: 2016, Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.*

Results indicate that the Natus Photic Stimulator complies with the applicable standards.

Performance Testing – Bench

The Natus Photic Stimulator 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 60601-2-40: 2016, Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.*
- *IEC 62366: 2007, Am1: 2014, Medical devices – Application of usability engineering to medical devices.*
- *IEC 62471: 2006, Photobiological safety of lamps and lamp systems.*
- *ANSI Z80.36-2016, Light Hazard Protection for Ophthalmic Instruments.*

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

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