September 23, 2021

Micromed S.p.A.
Marina Ruotolo
Regulatory Affairs
Via Giotto 2
Mogliano Veneto, Treviso 31021
Italy

Re: K211974
Trade/Device Name: LED PHOTIC System
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: June 21, 2021
Received: June 25, 2021

Dear Marina Ruotolo:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211974

Device Name
LED PHOTIC System

Indications for Use *(Describe)*
LED PHOTIC System is an accessory indicated for photic activation of brain during the electroencephalographic (EEG) studies. It always has to be used in combination with an EEG system, in order to evaluate particular anomalies of the brain activity due to the intermittent photic stimulation. The product must be used only by qualified personnel (physicians or technicians of neurophysiopathology) for the execution of EEG exams in a professional environment.

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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Traditional 510(k) Summary

Summary Date: 21 June 2021

Applicant Name: Micromed S.p.A.

Applicant Address: Via Giotto 2 Mogliano Veneto
Treviso, ITALY 31021

Submission Correspondent:

On behalf of Micromed S.p.A., the following consultant is assigned the responsibility of submission correspondence:

Marina Ruotolo, Regulatory Affairs
Via Giotto 2
Mogliano Veneto
Treviso, ITALY 31021

Trade Name: LED PHOTIC System

Common Name: Photic Simulator

Classification Name: 21 CFR 882.1890, GWE-Evoked Response Photic Stimulator

Device Class: Class II

Predicate Device: Lifelines Photic Stimulator (K101691), Lifelines Ltd.

Device Description: LED PHOTIC System is an accessory indicated for photic activation of brain during the electroencephalographic (EEG) studies. It is to be used in combination with an EEG system, in order to evaluate particular anomalies of the brain activity due to the intermittent photic stimulation.

The LED PHOTIC System is managed by the EEG system software for setting some parameters, IC, and the power supply called LED PHOTIC IC POWER is an integral part of the LED PHOTIC System.

Indications for Use: LED PHOTIC System is an accessory indicated for photic activation of brain during the electroencephalographic (EEG) studies. It always has to be used in combination with an EEG system, in order to evaluate particular anomalies of the brain activity due to the intermittent photic stimulation. The product must be used only by qualified personnel (physicians or technicians of neurophysiopathology) for the execution of EEG exams in a professional environment.

Comparison with Predicate Device:

Device & Predicate Device(s):	K211974	K101691	Comments
General Device Characteristics			
Intended Use	LED PHOTIC System is an accessory indicated for photic activation of brain during the electroencephalographic (EEG) studies. It always has to be used in combination with an EEG system, in order to	The Lifelines Photic Stimulator is indicated for photic activation of the EEG during an	Proposed IFU contains additional information, but IFU intent remains the same.

	evaluate particular anomalies of the brain activity due to the intermittent photic stimulation. The product must be used only by qualified personnel (physicians or technicians of neurophysiopathology) for the execution of EEG exams in a professional environment.	EEG study and in the generation of visual evoked potentials.	
Light output	Max 1.9 kLux at 10 cm/Max 1.1 kLux at 20 cm/Max 0.7 kLux at 30 cm	13 kLux at 1 ft.	Predicate device has lower Lux at similar distance.
Flash rate	0-60Hz	1-60Hz	Similar
Power supply	120Vpower (wall outlet) access required.	Can be powered via USB on host PC or power supply.	Similar
Software	Computer controlled (not included)	Computer controlled (software included)	Predicate device has software capabilities.

Performance Testing:

The LED PHOTIC System was tested and found compliant to the following safety standards:

- IEC 60601-1:2005 + A1:2012: Medical Electrical safety
- IEC 60601-1-6:2010 + A1:2013: Usability
- IEC 60601-2:2014: EMC Compliance
- IEC 62471:2006: Photobiological Safety

Conclusion: Based on performance testing and comparison to predicate performance, the LED PHOTIC system demonstrates substantial equivalence.