510(k) Summary
807.92(c)

K101691

SPONSOR

Company Name:	Lifelines Ltd.
Company Address	7 Clarendon Court Over Wallop, near Stockbridge Hampshire SO20 8HU United Kingdom
Telephone:	44.1264.782226
Fax:	44.1264.782088
Contact Person:	Stephen Walters

AUG 1 0 2010

Summary Preparation Date: June 14, 2010

DEVICE NAME

Trade Name:	Lifelines Photic Stimulator
Common/Usual Name:	Photic Stimulator
Classification Name:	Stimulator, Photic, Evoked Response
Regulation Number:	882.1890
Product Code:	GWE
Device Class:	Class II

PREDICATE DEVICE

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
EB Neuro, S.P.A.	BE Plus / AURA-LTM64 Amplifier	K053606

DEVICE DESCRIPTION

The Photic Stimulator is a device for generating short-duration flashes of white light by means of a solid-state LED (light emitting diode). The flashes are controlled from a host PC and typically occur over a repetition rate of between 1 and 60Hz.

DEVICE INDICATIONS FOR USE

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

12.1 Predicate Product Comparison Chart

Manufacturer	Lifelines Ltd.	EB Neuro, S.P.A.
Device Name	**Photic Stimulator**	**Model BE Plus / AURA--LTM64**
K Number	**K093153**	**K053606**
Intended Use	The Lifelines Photic Stimulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.	The BE Plus / AURA-LTM64 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations. .
Mode of Operation	Arm mounted Photic stimulator generates flashes of white light by means light emitting diode (LED.	Arm mounted photic stimulator generates flashes of white light by means light emitting diode (LED.
Specifications		
Light source	Single hi-intensity LED and associated optics	96 LEDs
Luminous Flux	700lm typical, 900 lm max 13,000 lux at 1 foot	144.0 lumens (minimum) 182.4 lumens (typical) 230.4 lumens (maximum)
Duration	1-10ms duration fised or auto duty cycle, 100ms max	5 ms
Interfaces		5-pin TRIAD male connector; Power supply, controlling signal (trigger)
Flash Rate	1-60Hz or single (manual) flash	Up to 60 per second, externally controlled
Input	TTL, USB, Serial	TTL level
Outputs	100mV isolated pulse	TTL level
Power	5 – 15V DC	12 VDC (±5%)
Compatibility	For use with Trackit system, NicoletOne system or any other compatible system providing interface to USB, TTL or serial control signals	For use with Grass Comet or AURA Base Station
Physical size	5" diameter x 5" long Weight 12 ozs.	Flash lamp: 8.25" W x 2.5" H x 2" D Weight 7.1 ozs. Adapter Box: 3.25" W x 1.75" H x 0.75" D Weight 1.8 ozs.

Flash Lamp Holder Specifications		
Weight	Base & Mast: 24.2 lbs. Arm: 1.7 lbs	Base & Mast: 24.2 lbs Arm: 1.6 lbs
Mast Height	39"	34.5"
Base Diameter	26"	24"
Arm Length	34"	34"
Safety Testing	EN/IEC 60601-1 EN/IEC 60601-1-2 UL60601-1 CAN/CSA-C22.2 No.601-1-M90	EN 60601-1, EN 60601-1-2 IEC 60825-1:1993+ A1: 1997 + A2:2001

SAFETY and EFFECTIVENESS

The Lifelines Photic Stimulator was compliant to the safety standards.
IEC 60601-1 Medical Electrical safety
IEC 60601-2 EMC compliance
ISO 15004-2 Light Hazard Protection

CONCLUSION

Lifelines Photic Stimulator is similar to the predicate device in

- intended use, .
- technological characteristics
- design.

The Lifelines Photic Stimulator is substantially equivalent to the predicate device and introduces no new questions concerning safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lifelines Ltd.
c/o Mr. E.J. Smith
Regulatory Consultant
Smith Associates
1468 Harwell Ave.
Crofton, MD 21114

AUG 10 2010

Re: K101691
Trade/Device Name: Lifelines Photic Stimulator
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: June 14, 2010
Received: June 16, 2010

Dear Mr. Mr. Smith:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101691

Indications for Use

510(k) Number (if known): K101691

Device Name: Photic Stimulator

AUG 10 2010

Indications for Use:

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

(Check appropriate designation below)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101691