DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

October 23, 2015

Lifelines Ltd.
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K151600
Trade/Device Name: R-40 EEG Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GWQ
Dated: September 11, 2015
Received: September 22, 2015

Dear Ms. 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 contact the Division of Industry and Consumer Education 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 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,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151600

Device Name
R-40 EEG Amplifier

Indications for Use *(Describe)*
The R-40 EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

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.

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510(k) Summary

SPONSOR

Company Name: Lifelines, Ltd.
Company Address: 7 Clarendon Court
Over Wallop, Hampshire
SO20 8HU United Kingdom

Telephone: +44 (0)1483 224 245
Contact Person: Michael Hulin

Summary Preparation Date: June 2, 2015

DEVICE NAME

Trade Name: R-40 EEG amplifier
Common/Usual Name: EEG Amplifier
Classification Name: Amplifier, Physiological Signal
Regulation Number**:** 21 CFR 882.1835
Product Code: GWL, GWQ
Device Class: Class II

PREDICATE DEVICE

Legally Marketed Equivalent Device

Company	***Product***	***510(k) #***
Carefusion 209, In.	Nicolet Wireless EEG Amplifier	K103140

DEVICE DESCRIPTION

The R-40 EEG Amplifier is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications.

It is a compact USB 40-channel amplifier which incorporates 32 referential channels and 8 polygraphic channels with built-in calibration and electrode impedance measurement. A Nonin pulse oximeter interface is provided, a Patient Event input, 2 Aux DC inputs and an Electrocap connector. Optional wireless communication is available (Bluetooth and WLAN WiFi).

The Amplifier is intended to be connected to a USB port on a PC which is powered from a medically approved power supply.

This equipment is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. The equipment does not sustain or support life.

DEVICE INDICATIONS FOR USE

The R-40 EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

COMPARISON OF TECHNICAL CHARACTERISTICS

The Indications for Use and Intended Use are identical to the predicate device.

The technological characteristics are substantially similar; the new device is based on existing, well established technologies and is intended for use in the established field of EEG. The differences between the new device and the predicate device are:

- The new device has a wider signal input voltage range which includes DC. Most EEG amplifiers are AC coupled which enables high gain to be applied to the small EEG signals. With the improvements to analog-to-digital resolution, the new device captures the DC component of the signal along with the small AC component. This provides useful additional EEG information for the neurophysiologist.
- The new device provides a connector for the attachment of an Electro-cap. This is an added convenience for the user. The Electro-cap has electrodes built in to a head-worn cap and is popular with some users.
- The new device can be powered from a USB port. The device has built-in electrical isolation for patient safety. Data can also been transferred via the USB port.
- The new device offers Bluetooth as an option. This provides short-range wireless communication with the host computer and offers an alternative means of data transfer.

These differences raise no new questions concerning safety or effectiveness. The Lifelines R-40 EEG Amplifier is substantially equivalent to the predicate device.

PERFORMANCE DATA

Safety Testing

IEC 60601-1: 2005+A1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance. Including US AAMI ES 60601-1:2005.
IEC60601-1-2:2007 Medical electrical equipment – Part 1-2: general requirements to basic safety and essential performance- Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-2-26:2012 Medical electrical equipment – Part 2: Particular requirements for the safety of electroencephalographs.

Clinical testing was not performed with this device.

CONCLUSION

The Lifeline R-40 EEG Amplifier meets the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the predicate device, Nicolet Wireless EEG Amplifier.