May 4, 2018

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

Re: K172271
Trade/Device Name: Trackit T4 EEG Amplifier
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWL
Dated: April 5, 2018
Received: April 10, 2018

Dear Yolanda 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.

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 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)*
K172271

Device Name
Trackit T4 EEG Amplifier

Indications for Use *(Describe)*
The Trackit T4 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

SPONSOR

Company Name:	Lifelines, Ltd.
Lif	
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: July 17, 2017

DEVICE NAME

Trade Name:	Trackit T4 EEG amplifier:
Common/Usual Name:	EEG Amplifier
Classification Name:	Electroencephalograph
Regulation Number**:**	21 CFR 882.1400
Product Code:	GWQ, GWL
Device Class:	Class II

PREDICATE DEVICE

Legally Marketed Equivalent Device

Company	***Product***	***510(k) #***
Lifelines, Ltd.	R40 EEG Amplifier	K151600

DEVICE DESCRIPTION

The Trackit T4 EEG Amplifier is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications and due to its small size, can be used in ambulatory applications. In this situation, the EEG electrodes are fitted to the patient by a trained clinician prior to the patient being sent home. No subsequent intervention is required by the patient. Upon completion of the recording, the data which is stored on a memory card is reviewed by a clinician using review and analysis software on a PC.

It is a compact USB amplifier which provides 32 channels (or 68 channels with internal expansion option) with built-in calibration and electrode impedance measurement. Also provided is a Nonin pulse oximeter interface, a Patient Event input and an Aux DC input. Optional wireless communication is available (Bluetooth and WLAN WiFi).

There are two variants of the Trackit T4 EEG Amplifier:

- Trackit T4-32 providing 24 referential + 8 poly channels.
- Trackit T4-68 providing 64 referential + 4 poly channels (using internal expansion board).

Plug-on Patient Connection Units (PCUs) provide 32 channel touchproof inputs (model T4-PCU 24+8) or 68 channels (model T4-PCU 64+4).

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

approved power supply. In addition it can be battery powered in ambulatory applications.
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 Trackit T4 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 following chart compares the new T4 EEG Amplifier with the company's R-40 EEG Amplifier as the predicate device. The new device has evolved from the R-40 with the goal of making it suitable for ambulatory and home use. Differences in characteristics are discussed in the notes in the following section.

	New device: **Lifelines T4 EEG Amplifier**	**Predicate device:** **Lifelines R-40 EEG Amplifier**	**Similarities and Differences**
Product Code	GWL and GWQ	GWL and GWQ	Same
510(k) no.	New device	K151600	
Indications for Use	The T4 EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).	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).	Same
Description of device	The T4 EEG Amplifier is a stand-alone 32 channel (24 EEG + 8 poly) EEG amplifier with built-in calibration and electrode impedance measurement. It is expandable to 68 channels with an internal expansion board.	The R-40 EEG Amplifier is a stand-alone 40 channel (32 EEG + 8 poly) EEG amplifier with built-in calibration and electrode impedance measurement.	New device has 32 channels instead of 40. Expandable to 68[note 5].
	The device can be powered from an external battery pack for ambulatory usage. No intervention is required by the patient.		Added ambulatory usage with external battery pack[note 3].
	A Nonin XPOD interface is provided for pulse oximetry. A USB connection is used to communicate with the host computer with the option of wireless (Bluetooth and WiFi).	A Nonin XPOD interface is provided for pulse oximetry. A USB connection is used to communicate with the host computer with the option of wireless (Bluetooth and WiFi).	) Same))))))
	There are no physiological alarms.	There are no physiological alarms.	))

	New device: **Lifelines T4 EEG Amplifier**	**Predicate device:** **Lifelines R-40 EEG Amplifier**	**Similarities and Differences**
Clinical Application Environment	For use in research institutions, clinic, hospital, operating room and epilepsy evaluation environments. Home use.	For use in research institutions, clinic, hospital, operating room and epilepsy evaluation environments.	) Same)))) Addition of home use[note 8].
Intended User	A healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice.	A healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice.	Same
Channels	24 EEG + 8 bipolar + SpO2 + patient event button. (64 EEG + 4 bipolar with internal expansion board).	32 EEG + 8 bipolar + SpO2 + patient event button.	Reduced number of channels in order to reduce the size of the device. Optional expansion available[note 5].
ADC resolution	24 bits	24 bits	Same
Full-scale input	± 375 mV	± 375 mV	Same
Sampling rate	250 - 16000 Hz	250 - 16000 Hz	Same
Input noise	< 1.5 µV pk-pk	< 1.5 µV pk-pk	Same
Bandwidth (-3dB)	DC to 4193 Hz max.	DC to 4193 Hz max.	Same
Calibration	8000 µV at 1 sec period	8000 µV at 1 sec period	Same
Impedance pass/fail levels	2, 5, 10, 20, 50 kΩ limits adjustable on host computer during setup.	2, 5, 10, 20, 50 kΩ limits adjustable on front panel.	Facility removed from front panel to reduce the size of the device[note 7].
SaO2 input	Yes	Yes	Same
E-Cap connector	No	Yes	E-Cap connector has been removed to reduce the size of the device[note 6].
Front panel display	Displays battery capacity, elapsed recording time, wireless connection status.	No	Added display shows device status during ambulatory usage[note 4].
Host PC communicat-ion	Wired (USB) or Wireless (802.11b/g) or Bluetooth	Wired (USB) or Wireless (802.11b/g) or Bluetooth	Same
Power	USB (isolated from patient) or external battery pack	USB (isolated from patient) or battery	New device can be powered from external battery pack for ambulatory usage[note 3].
Internal storage	micro-SD flash card	micro-SD flash card	Same

	New device: **Lifelines T4 EEG Amplifier**	**Predicate device:** **Lifelines R-40 EEG Amplifier**	**Similarities and Differences**
Internal battery	Li-ion rechargeable	Li-ion rechargeable	Same
Patient event button input	Yes	Yes	Same
System components	Amplifier, laptop PC, medical grade power supply, Nonin oximeter, patient event button. Bag and straps.	Amplifier, laptop PC, medical grade power supply, Nonin oximeter, patient event button.	) Same))) Bag for ambulatory usage[note 8].
Material	ABS	ABS	Same
Patient contact	Device does not directly contact the patient. EEG electrodes (not supplied) are patient-applied.	Device does not directly contact the patient. EEG electrodes (not supplied) are patient-applied.	Same
Size	9 x 17 x 3 cm	11 x 17 x 4 cm	New device is smaller[note 1].
Weight	270 gm	400 gm	New device is lighter[note 1].
Compliance/ regulatory	IEC 60601-1 + ANSI + CAN IEC 60601-2-26 IEC 60601-1-2 CE Mark IEC 60601-1-11	IEC 60601-1 + ANSI + CAN IEC 60601-2-26 IEC 60601-1-2 CE Mark	) Same))) Addition of IEC 60601-1-11 Home Use[note 8].

Similarities and Differences

The technological characteristics are substantially similar; the new device has evolved from the R-40 with the intention of making it suitable for ambulatory and home use. It 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:

1. The new device uses the same internal electronics as the R-40 but its case has been reduced in size to make it more suitable for ambulatory use.
2. The Indications for Use for the new device are the same as the R-40.
3. The new device can be powered from an external power pack for ambulatory use.
4. The new device incorporates a small alpha-numeric display which shows battery capacity, elapsed recording time and wireless connection status during ambulatory use.
5. The channel count has been reduced from 40 to 32 in order to reduce the size of the device to optimize it for ambulatory use. The channel count can optionally be increased to 68 with an internal expansion board, for more complex clinical examinations.
6. The Electro-cap connector has been removed in order to reduce the size of the device to optimize it for ambulatory use.
7. The front-panel impedance limit feature has been removed. Impedance limits can be adjusted on the host computer during set-up.
8. The new device is suitable for ambulatory and home use.

These differences raise no new questions concerning safety or effectiveness. The Lifelines T4 EEG Amplifier is substantially equivalent to the predicate device.

Pre-clinical Performance Testing

The table below provides details of the bench testing performed on the T4 EEG Amplifier. Comparison is provided with the predicate device (R-40 Amp) in order to establish substantial equivalence.

Test	Test Method	Test specification		Conclusion
		T4 subject device[1]	R-40 predicate device[2]	
Insulation resistance	Using an insulation tester measure the resistance between the TF1 'Aux. B' socket and the metalwork of the USB plug. Ensure that it is > 200 MΩ.	3.1	3.1	Same test as predicate
Dielectric strength	Connect a breakdown tester. Increase the voltage slowly over 10s to 1500Vrms and hold it for 1 minute. Ensure that there are no signs of flash-over or breakdown.	3.2	3.2	Same test as predicate
Mains on Applied Parts	Measure the Mains on Applied Parts leakage current. Ensure that it is ≤ 5000uA AC.	3.6	3.6	Same test as predicate
Patient leakage	Measure the Patient leakage current. Ensure that it is ≤100uA AC and ≤10uA DC.	3.8	3.8	Same test as predicate
Calibration	Check for 8mVpp ±0.4 square wave signals on all channels at 1Hz frequency.	4.4	4.4	Same test as predicate
Short circuit noise	Check that the short circuit noise for all channels is < 1.5uVpp.	4.8	4.7	Same test as predicate
HF response	Check HF response to 80 Hz.	4.10	4.9	Same test as predicate
DC response	Check for a +300mV step and a -300mV step.	4.11	4.10	Same test as predicate
Impedance check	Check all channels indicate an impedance of 3000Ω ±500.	4.16	4.15	Predicate has front-panel LEDs. Otherwise same.

[1] Clause numbers in T4-32 Amp Final Test Specification

[2] Clause numbers in R-40 Amp Final Test Specification

PERFORMANCE DATA

Testing was undertaken by an independent certification body and provided confirmation that the device performance and physical attributes met the requirements of the standards listed below. These standards address safety, EMC compatibility, risk, usability and home use.

Verification and validation testing confirmed that this device met the design requirements and user needs.

Safety Testing

12.4.1 IEC 60601-1:2012. *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Including ANSI/AAMI and CAN/CSA.*

12.4.2 IEC 60601-2-26:2012. *Medical electrical equipment. Particular requirements for the safety of electroencephalographs.*

12.4.3 IEC 60601-1-2:2007. *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility.*

12.4.4 IEC 60601-1-6:2010 + A1:2013. *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.*

12.4.5 IEC 62366:2007 + A1:2014. *Application of usability engineering to medical devices.*

12.4.6 IEC 60601-1-11:2015. *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment & medical electrical systems used in the home healthcare environment*. *Including ANSI/AAMI and CAN/CSA.*

12.4.7 ISO 14971:2007. *Application of risk management to medical devices*.

12.4.8 IEC 62133:2012. *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*.

12.4.9 UN/DOT 38.3. *Transportation testing for lithium batteries*.

Clinical testing was not performed with this device.

CONCLUSION

The Lifelines Trackit T4 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.