Section 5

510(k) Summary

SPONSOR

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Summary Preparation Date: July 17, 2017

DEVICE NAME

Trade Name:	Trackit T4 EEG amplifier:
Common/Usual Name:	EEG Amplifier
Classification Name:	Amplifier, Physiological Signal
Regulation Number**:**	21 CFR 882.1400
Product Code:	GWL, GWQ
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.

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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 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:

- 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.
- The Indications for Use for the new device are the same as the R-40.
- The new device can be powered from an external power pack for ambulatory use.
- The new device incorporates a small alpha-numeric display which shows battery capacity, elapsed recording time and wireless connection status during ambulatory use.
- 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.
- The Electro-cap connector has been removed in order to reduce the size of the device to optimize it for ambulatory use.
- The front-panel impedance limit feature has been removed. Impedance limits can be adjusted on the host computer during set-up.

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

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.