February 9, 2023

Compumedics Limited
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K230073
Trade/Device Name: Okti
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: January 6, 2023
Received: January 10, 2023

Dear Dave Yungvirt:

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,

Patrick Antkowiak -S

for
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)*

Device Name
Okti

Indications for Use *(Describe)*
The Okti System is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various neurological disorders. The Okti is designed for use in a hospital or other clinical environment. The Okti is only to be used under the direction of a physician.

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

Device Name: Okti

The following 510(k) summary is being submitted in accordance with 21 CFR 807.92.

Submission Details

Applicant Information:

Submitter: Compumedics Limited
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Submission Prepared: *02/11/2022*

Subject Device Information:

Trade name: Okti
Common name: Okti
Primary Product code: GWQ
Classification Names: Full-Montage Standard Electroencephalograph
Panel: Neurology
Device class: II
Regulation numbers: 21 CFR 882.1400

Predicate Device Information

Trade Name: Grael System
Model: Grael EEG
Manufacturer: Compumedics Limited
510(k) number: K093223
510(k) Decision Date: 15th January 2010
Classification: Full-Montage Standard Electroencephalograph, Ventilatory Effort Recorder
Product code: GWQ, MNR
Device class: II
Regulation numbers: 21 CFR 882.1400

Intended Use / Indications For Use

The Okti System is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various neurological disorders. The Okti is designed for use in a hospital or other clinical environment. The Okti is only to be used under the direction of a physician.

Device Description

The Okti is a physiological data acquisition device intended for conducting EEG studies. It is used in conjunction with a PC running Compumedics Profusion EEG software. Power is provided by either an internal Lithium-Ion battery or a POE 100BASE-TX network connection.

Physically, the Okti comprises a base unit housing the battery and digital electronic circuits. A changeable module connects to the base unit and houses the analogue circuity and electrode connectors providing options for 32, 64 or 128 referential, or single ended, channels primarily intended for EEG. Each module includes several differential inputs for electrode-based signals such as ECG, EMG or EOG. All these inputs are class CF for patient safety.

Patient physiological data is digitised using multiple 24-bit ADCs and filtered using fixed point FIR filters implemented internally to an FPGA located in the analogue module. The data is transferred to a general-purpose processor in the base unit over a synchronous serial link. From there the patient data may be saved to a device internal SD card or sent to a remote PC over an Ethernet or Wi-Fi LAN connection. A Bluetooth interface is also included for connection to external devices such as an oximeter.

The Okti system is available in Okti32, Okti64, or Okti128. These differ only in channel number with below characteristics.

Model	Inputs
Okti32	32, DC-coupled, fully isolated, referential (monopolar); 8 user-defined, DC-coupled, fully isolated, bipolar inputs
Okti64	64, DC-coupled, fully isolated, referential (monopolar); 4 user-defined, DC-coupled, fully isolated, bipolar inputs
Okti128	128, DC-coupled, fully isolated, referential (monopolar); 8 user-defined, DC-coupled, fully isolated, bipolar inputs

Comparison to Predicate Device

The Okti's predicate device is the Grael System. The Grael (K093223) comprises two primary models: the Grael, is a full channel device suitable for conducting either PSG or EEG studies; and the Grael EEG, a reduced channel device suitable for EEG studies only.

The Grael EEG is optimized for neurological studies, and does not contain inputs used for respiratory monitoring during PSG which are not necessary for neurological studies. The Grael EEG model is the predicate device and claims relating to PSG are not being made for the Okti.

Characteristic	Okti	Grael EEG
Usage		
510(k) Number	-	K093223
Classification	882.1400	882.1400
Product Code	GWQ	GWQ
Class	II	II
Intended Use	EEG studies to assist in the diagnosis of various neurological disorders	EEG studies to assist in the diagnosis of various neurological disorders
Type of Use	Prescription Only	Prescription Only
Use Environment	Hospital / Clinical use only	Hospital / Clinical use only
Temperature	-10°C to 50°C storage/non-operating 0°C to 40°C operating	-10°C to 50°C storage/non-operating 0°C to 40°C operating

Relative Humidity	20 to 90% relative humidity non-condensing	20 to 90% relative humidity non-condensing
Altitude	< 3000m	< 3000m
Physical Specifications		
Dimensions	Base unit: 84mm x 43mm x 184mm Amplifier module: 32ch 84mm x 26mm x 150mm 64-ch: 84mm x 25mm x 150mm 128-ch: 84mm x 33mm x 150mm	Amplifier: 240mm x 144mm x 50mm Jackbox: 200mm x 83.1mm x 49mm
Mass	Base unit: < 225g battery not fitted < 555g battery fitted Amplifier module weight: 32ch < 145g 64-ch < 170g 128ch < 155g	Amplifier: < 700g Jackbox: < 700g
Electrical Specifications		
Power Supply	Power is provided by either rechargeable Lithium-ion battery (6400 mAH, > 300 charge/discharge cycle at 23°C, 11.25 volts) or Power Over Ethernet (either mid-span injector or PoE switch, per IEEE 802.3af standard)	All power provided by the network connection using Power Over Ethernet (either mid-span injector or PoE switch, per IEEE 802.3af standard)
Operating Voltage	48 Volts	48 Volts
Power Consumption	< 4 Watts	< 10 Watts
Channel Specifications		
Input Impedance	> 100 MΩ all channels	> 100 MΩ channels 1-32 > 20 MΩ channels 33-40
Bias Current	Typically 1nA	Typically 1nA
Input Noise	< 2µV peak-to-peak typical (referential)	< 2 µV peak-to-peak typical (referential)
Input Range	User Selectable: 300mV peak-to-peak 600mV peak-to-peak 1200mV peak-to-peak 3000mV peak-to-peak	User selectable: 300mV peak-to-peak 600mV peak-to-peak 1200mV peak-to-peak 3000mV peak-to-peak
CMRR	> 100dB	> 100dB
Crosstalk	< -60dB	< -60dB
High Pass Filter	DC Coupled all channels	DC Coupled on all channels
Low Pass Filter	3dB cut-off frequency (f_c) at sampling rate (F_s): f_c = 71 Hz, F_s = 256 Hz f_c = 143 Hz, F_s = 512 Hz f_c = 284 Hz, F_s = 1024 Hz f_c = 580 Hz, F_s= 2048 Hz f_c = 1150 Hz, F_s= 4096 Hz	3dB cut-off frequency (f_c) at sampling rate (F_s): f_c = 71 Hz, F_s = 256 Hz f_c = 143 Hz, F_s = 512 Hz f_c = 284 Hz, F_s = 1024 Hz f_c = 580 Hz, F_s= 2048 Hz f_c = 1150 Hz, F_s= 4096 Hz
Notch Filter	Software based display filtering of 50Hz, 60Hz or off	Software based filtering of 50Hz, 60Hz or off
Isolation Specifications	Complies with IEC 60601-1 CF patient inputs	Complies with IEC 60601-1 CF patient inputs

Analogue to Digital Converter	24 bit resolution	24 bit resolution
Sample and Data rates	Data sampled at 16384 samples per second and decimated to data rates shown below. Actual data rate sent is determined by controlling PC software application. Output data rates of 4096, 2048, 1025, 512 or 256 samples per second.	Data sampled at 16384 samples per second and decimated to data rates shown below. Actual data rate sent is determined by controlling PC software application. Output data rates: 4096, 2048, 1024, 512, or 256 samples per second.
Communication Interface		
Software	Profusion EEG for amplifier configuration, data acquisition, and display	Profusion EEG for amplifier configuration, data acquisition, and display
Network Types	IEEE 802.3/802.3u Ethernet, auto MDIX Requires an IEEE 802.3af compliant switch or mid-span power injector and network isolator Wi-Fi interface IEEE 802.11a, 802.11b, 802.11g and 802.11n compatible	802.3/802.3u twisted pair Ethernet with auto MDIX; RJ45 connector

Summary of Performance Data

An extensive collection of tests have been conducted and successfully completed including,

- Electrical Safety Testing as per IEC 60601-1:2005. These ensure there is no potential for detrimental effects on patients, other persons, animals or the surroundings. They relate particularly to aspects concerning electrical safety such as means of operator protection, protection against electric shock and other hazards; as well as mechanical aspects such as construction and protection against spillage.
- Electromagnetic Compatibility Testing as per IEC 60601-1-2, and modification by the listed particular and collateral standards. These EMC tests were designed to verify that device emissions are in accordance with allowable limits, as well as device immunity against electrical and magnetic phenomena which may be expected to encounter in line with its intended use.
- Electroencephalograph safety and performance testing as per IEC 80601-2-26. Testing against the particular standard for electroencephalograph includes validation against multiple essential performance requirements such as accuracy of amplitude and rate of variation signal reproduction, input dynamic range and differential offset voltage, input noise, frequency response, and common mode rejection ratio.
- Bench testing against Okti functional requirements to ensure that performance meets hardware and software design specifications

Further details such as device specifications, test requirements, acceptance criteria, results, and evaluation are available throughout this 510(k) submission. All tests passed with results equivalent to the Grael, and did not raise additional concerns of safety and effectiveness.

Conclusion

Compumedics Ltd. considers the Okti to be substantially equivalent to its predicate devices the Grael System, specifically the Grael EEG model. The indications for use, technological characteristics, and

underlying principles of operation are the same. There are no questions of safety and effectiveness, and substantial equivalence is supported by extensive performance testing data.