February 20, 2025

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

Re: K242447
Trade/Device Name: Falcon HST
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, OMC, MNR
Dated: December 20, 2024
Received: December 20, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jay R. Gupta -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Falcon HST

Indications for Use *(Describe)*

The Falcon HST is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.

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.

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AJ231 Falcon HST 510(k) Summary

Device Name: Falcon HST

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

Submission Details

Applicant Information:

Submitter: Compumedics Limited
Address: 30-40 Flockhart Street, Abbotsford 3067, Victoria, Australia
Phone number: +61 (0) 3 8420 7300
Fax number: +61 (0) 3 8420 7399

Contact person: John Joseph
Address: 30-40 Flockhart Street, Abbotsford 3067, Victoria, Australia
Phone number: +61 (0) 3 8420 7362
Fax number: + 61 (0) 3 8420 7399
Email: jjoseph@compumedics.com.au

Submission Prepared: November 25, 2024

Subject Device Information:

Trade name: Falcon HST
Common name: Falcon HST
Primary Product code: OLV, OMC, MNR
Classification Names: Electroencephalograph
Panel: Neurological Devices
Device class: II
Regulation numbers: 21 CFR 882.1400

Predicate Device Information

Primary Predicate Device:

Trade Name: Zmachine Synergy
Manufacturer: Consolidated Research of Richmond, Inc.
510(k) number: K172986
510(k) Decision Date: 19th Dec 2017
Classification: Electroencephalograph
Product code: OLV, OMC, MNR
Device class: II
Regulation numbers: 21 CFR 882.1400

Secondary Predicate Device:

Trade Name: Zmachine DT-100
Manufacturer: Consolidated Research of Richmond, Inc.
510(k) number: K101830
510(k) Decision Date: 31st Mar 2011
Classification: Electroencephalograph
Product code: OLV, OMC
Device class: II
Regulation numbers: 21 CFR 882.1400

Intended Use / Indications For Use

The Falcon HST is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.

Device Description

The Falcon HST comprises hardware and software which provide separate parameters for recording, review, and analysis of collected and stored physiological parameters, including EEG, EOG, ECG and respiratory signals, which are then used as an aid in the diagnosis of respiratory and/or cardiac related sleep disorders by qualified physicians.

The Falcon system consists of the main unit and the charging cradle. The main unit is a small device that is worn on the patient's chest over clothing. It is equipped with a touch-screen LCD and contains various channel inputs such as for the inductive plethysmography bands, and electrodes. The Falcon charging cradle is used to charge the device, as well as provide a USB interface for transferring study data to the PC.

Technology overview

Electroencephalograph (EEG)
Both Falcon HST and Zmachine Synergy use the same EEG hardware to acquire an EEG channel characteristic.

Respiratory effort
Respiratory Effort is sensed by the Falcon HST using a thoracic and abdominal effort belt, however Zmachine Synergy uses only a thoracic effort belt to record chest expansion and contraction during inhalation and exhalation (i.e. respiratory effort).

Respiratory nasal airflow
Both Falcon HST and Zmachine Synergy use the similar pressure transducer to acquire the respiratory nasal airflow signals.

Body position
Both the Falcon HST and Zmachine Synergy use solid-state accelerometer to acquire the body position signal.

Blood oxygen saturation and pulse
Both the Falcon HST and Zmachine Synergy use the similar pulse oximeter hardware and data output modes to acquire the blood oxygen saturation and pulse signals.

PC Software

The Falcon HST device is compatible with Profusion Sleep software v5.1 or greater, while the predicate device Zmachine DT-100 (K101830) is compatible with their analysis software. The main differences involve the addition of Falcon HST file format support and data retrieval.
Profusion PSG software 5.1 is identical to the Profusion PSG software which was separately cleared as a part of K072201 and K093223, and as a result, required software documentation is provided regarding this software.

The differences in software versions do not constitute a substantial change as they are not changes to underlying software specifications and are instead driver-level changes necessary for data conversion from the Falcon HST device. The system has been subject to functional testing with full coverage of data flow paths including USB communication which represents the predominant change between versions. Additionally, the Profusion Sleep interface has been used as part of the system setup for IEC 60601-1-2 and IEC 80601-2-26 tests as these include tests relating to signal display and accuracy of signal reproduction, especially in a noisy environment.

Substantial Equivalence

This document represents the discussion of the substantial equivalence of the Falcon HST with respect to its primary predicate device the Zmachine Synergy (K172986). To discuss the substantial equivalence of Profusion Sleep 5.1 software feature support to Falcon HST, another predicate device Zmachine DT-100 (K101830) is included as Zmachine Synergy (K172986) only focuses on hardware device application. Additionally, this document provides a comparison of intended use, as well as a comprehensive evaluation of technological characteristics. Available performance data is summarised to further support safety and effectiveness and substantial equivalence with respect to its predicate devices.

The Zmachine Synergy device was launched in 2017 by Consolidated Research of Richmond, Inc. It has been sold in respective markets since then. The intended use of the Falcon HST is the same as the Zmachine Synergy, as is the channels recorded and the basic use and technology.

The main differences are that the Falcon HST is a single unit with colour touch screen rather than a single button configuration in the Zmachine Synergy. The Falcon HST has a charging cradle unlike Zmachine Synergy which has a USB charging cable.

Based on the Indications for Use, results of technological, performance & safety testing and a comparison to the predicate devices, it is concluded that the Falcon HST system with Profusion Sleep 5.1 feature support is substantially equivalent to the Zmachine Synergy and Zmachine DT-100, and there are no new issues identified in terms of safety or effectiveness with respect to its intended use.

The below table contains a multi-parameter comparison between Falcon HST system with Profusion Sleep 5.1 support feature, the primary predicate device the Zmachine Synergy and the predicate device Zmachine DT-100. This table is included in AJ056 Falcon Substantial Equivalence Discussion with further analysis of differences where applicable.

Characteristic	Falcon HST	Zmachine Synergy (Primary predicate device)	Zmachine DT-100 (Predicate device)
Usage Information			
Manufacturer	Compumedics Ltd.	Consolidated Research of Richmond, Inc.	Consolidated Research of Richmond, Inc.
510(k) Number		K172986	K101830
Classification regulation	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.1400
Product Code	OLV, OMC, MNR	OLV, OMC, MNR	OLV and OMC
Indications for use	The Falcon HST is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.	The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.	The CRI Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.

Type of Use	Prescription-Use Only	Prescription-Use Only	Prescription-Use Only
Intended Environment	Home or clinical environment	Home or clinical environment	Home or clinical environment
Patient Population	Adults	Adults	Adults
Acquired Channels	Airflow Pulse Oximeter Respiratory Effort Body Position EEG	Airflow Pulse Oximeter Respiratory Effort Body Position EEG	EEG
Sensor technology	Airflow: Solid state pressure transducer (±6 mbar range) Pulse Oximetry: Nonin 3150 Wrist-Ox2, BLE module. Respiratory Effort: Thoracic effort belt based on respiratory inductance plethysmography (RIP). Body position: Solid state accelerometer, multiple differential EXG channels.	Airflow: Solid state pressure transducer (±6 mbar range) Pulse Oximetry: Nonin XPOD LP module. Respiratory Effort: Thoracic effort belt based on respiratory inductance plethysmography (RIP). Body position: Solid state accelerometer, multiple EEG channels.	Zmachine DT-100 EEG technology
Sensor technology	LED indicators. A single colour LED is provided to indicate unit status. This LED is turned on or off (either continuously or flashing) under control of the firmware. The displayable colour is blue.	LED indicators. A full-color LED indicator is located beside each connector (airflow, effort, oximeter, and EEG) to indicate correct or incorrect hookup/operation. Another full-color LED is located under the main power button to indicate system status.	LCD display. A full color, 320×240 pixel, LCD display with an LED backlight is used to present all system information.
Power Source	Internally powered using li-ion rechargeable battery	Internally powered using li-ion rechargeable battery	Internally powered using li-ion rechargeable battery
Internal memory/ data Storage	Storage on Falcon HST onboard memory	Fixed microSD card	Removeable microSD card
Communication Interface	USB-C	USB	USB card reader
Access to recorded data	Recorded data is stored in the device. When the device is connected to PC via USB cable the device provides access to its internal memory.	Recorded data is stored in the device. When the device is connected to PC via USB cable the device provides access to its internal memory.	Recorded data is stored in the device. The microSD card is removed and connected to PC via USB card reader to access internal memory.
Recorded data format	Each channel of recorded data is stored in an individual file of the proprietary data format.	Each channel of recorded data is stored in an individual file of the GSC2 data format.	Each channel of recorded data is stored in an individual file of the binary data format.
Device dimensions	92 x 78 x 11 mm	120 x 61 x 24 mm	116 x 68 x 21 mm
Type of Device	EEG-based sleep monitor	EEG-based sleep monitor	EEG-based sleep monitor
No. of EEG Channels	4	1	1
Electrode Placement	Mastoid	Mastoid	Mastoid
Analyze EEG Data in Real time	Yes	n/a	Yes
Sleep Classification	Wake and Sleep	Wake and Sleep	Wake and Sleep

EEG Analysis Methodology	Proprietary adaptive algorithm using time and frequency domain features	n/a	Proprietary adaptive algorithm using time and frequency domain features
Can Provide Information to Assist the Physician in Diagnosis of Sleep Disorders?	Yes	n/a	Yes
Can Provide Information to Assist the Physician in the Application of Treatment	Yes	n/a	Yes
Provide Information to Assist Physician in the Evaluation of Treatment Efficacy?	Yes	n/a	Yes
Calculates Summary Sleep Statistics?	Yes	n/a	Yes
Battery Powered?	Yes	Yes	Yes

The table above shows that there are no significant differences between Zmachine Synergy and the predicate devices that adversely affect product safety and effectiveness.

Testing Summary

Design and verification activities have been performed on the Falcon HST as a result of the risk analysis and product requirements. External tests have been completed for electrical safety (IEC 60601-1:2005 (Third Edition) + COR1:2006 + COR2:2007 + A1:2012 + A2:2020), EMC (IEC 60601-1-2:2014 + A1:2020, EN 60601-1-2:2015+A1:2021), and mechanical and environmental requirements (IEC 60601-1-11:2015+A1:2020). In addition, side-by-side bench comparison testing summarized in the table below, was performed in which a Falcon HST was compared against a Zmachine Synergy (K172986).

Test	Test Method Summary	Results
EEG Input Circuit	EEG is sensed by the Falcon HST and Zmachine Synergy using the identical EEG amplifier and analog-to-digital conversion hardware. As such, the acquired signals from both systems are expected to be substantially equivalent. To test, an arbitrary waveform generator was connected to the EEG input of a Falcon HST and Zmachine Synergy device. Signals were generated by connecting this arbitrary waveform generator to the systems electrodes. Tests were not	The EEG characteristics were found to be in high agreement with the design limits for all points of comparison. As such, the EEG recording capabilities were found to be substantially equivalent.

	performed simultaneously, as waveforms were able to be replicated for each test using the same waveform generator.	
Respiratory Effort	Respiratory Effort is sensed by the Falcon HST using a thoracic and abdominal effort belt, however Zmachine Synergy uses only a thoracic effort belt to record chest expansion and contraction during inhalation and exhalation (i.e. respiratory effort). To test, the Falcon HST and Zmachine Synergy were subject to simulated inhalation and exhalation. As such, the acquired signals from both systems are expected to be substantially equivalent.	The acquired data from each system was analyzed in order to compare the Respiratory Effort readings. Both units produced similar readings. As such, the Respiratory Effort characteristics were found to be substantially equivalent.
Respiratory Airflow	Respiratory Airflow is sensed by the Falcon HST and Zmachine Synergy using the similar pressure transducer hardware. As such, the acquired signals from both systems are expected to be substantially equivalent. Testing required use of nasal cannula in the same setting with the same breathing rate for both products. The acquired signals from both systems are expected to be substantially equivalent.	The acquired data from each system was analyzed in order to compare the Respiratory Airflow readings. Both units produced similar readings. As such, the Respiratory Airflow characteristics were found to be substantially equivalent.
Body Position	Body Position is sensed by the Falcon HST and Zmachine Synergy using an accelerometer module. As both systems are measuring the angle of the system with respect to gravity, and both systems are worn by the patient in the same configuration, the acquired signal from both systems are expected to be substantially equivalent if it can be demonstrated that the Falcon HST reports angle with regard to gravity appropriately against an angular reference. To test, the Falcon HST and Zmachine Synergy devices are rotated through 360 degrees against an angular reference.	The acquired data from the Falcon HST and Zmachine Synergy was analyzed in order to compare the appropriate body position readings. As such, the Body Position recording capabilities were found to be substantially equivalent.
Pulse Oximetry	Pulse Oximetry is sensed by the Falcon HST and Zmachine Synergy using identical pulse oximeter hardware and similar data output modes. The device used was a NOnin Medical 3150 WristOx, being FDA approved as per FDA 510K Nonin Medical 3150 WristOx – K102350 As such, the acquired signals from both are expected to be substantially equivalent. Testing was performed by attaching the pulse oximeter	The acquired data from each system was analysed in order to compare the Pulse Oximeter readings. The heart rate and oxygen saturation readings were found to be in high agreement when comparing the two systems together. As such, the Pulse Oximeter recording capabilities were found to be substantially equivalent.

	to the index finger and obtaining a reading from the device one at a time, under the same conditions. As such, the acquired signals from both systems are expected to be substantially equivalent.	Both units produced similar readings. As such, the Pulse Oximeter recording capabilities were found to be substantially equivalent.

Additionally, following performance test was performed:

- Electroencephalograph safety and performance testing as per IEC 80601-2-26:2019. 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.
- Ambulatory Electrocardiography systems safety and essential performance testing as per IEC 60601-2-47:2012.
- 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 - Part 2: Lithium systems IEC 62133-2:2017/AMD1:2021
- Bench testing against Falcon functional requirements to ensure that performance meets hardware and software design specifications including functionality substantially equivalent to the Zmachine Synergy predicate device.

All tests passed with results equivalent to the Zmachine Synergy and Zmachine DT-100 and did not raise additional concerns of safety and effectiveness. Clinical performance testing was provided to validate that the performance of the Profusion PSG software 5.1 produces substantially equivalent results for calculating the apnea hypopnea index (AHI) and sleep staging (N1, N2, N3, REM and Wake) when compared to expert review of gold standard polysomnography data.

Conclusion

Compumedics Ltd. considers the Falcon HST to be substantially equivalent to its primary predicate device the Zmachine Synergy and predicate device the Zmachine DT-100. 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.