July 6, 2022

Cerebra Medical Ltd.
℅ Mary Vater
Associate Regulatory Consultant
Medical Device Academy Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K213007
Trade/Device Name: Cerebra Sleep System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, OLV, OLZ
Dated: June 3, 2022
Received: June 6, 2022

Dear Mary Vater:

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,

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
Cerebra Sleep System

Indications for Use *(Describe)*

The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration. The Cerebra Sleep System is for prescription use in a home or healthcare facility.

The Cerebra Sleep System is intended to be used as a support tool by physicians and PSG technologists to aid in the evaluation and diagnosis of sleep disorders. It is intended to provide sleep-related information that is interpreted by a qualified physician to render findings and/or diagnosis, but it does not directly generate a diagnosis.

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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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Cerebra Medical Ltd.
1470 Willson Place, Unit B
Winnipeg, Manitoba, CA R3T 3N9
+1.431.801.0332

Contact Person: Mary Vater
Date Prepared: July 6, 2022

II. DEVICE

Name of Device: Cerebra Sleep System
Classification Name: Reduced-Montage Standard Electroencephalograph
Regulation: 21 CFR §882.1400
Regulatory Class: Class II
Product Classification Code: OMC, OLV, OLZ

III. PREDICATE DEVICE

Primary Predicate Manufacturer: Advanced Brain Monitoring, Inc.
Primary Predicate Trade Name: X8 System - Sleep Profiler (SP40), X8 System – Sleep Profiler PSG2 (SP29), X8 System - Stat X8 (XS29)
Primary Predicate 510(k): K152040

Secondary Predicate Manufacturer: Younes Sleep Technologies
Secondary Predicate Trade Name: Michele Sleep Scoring Systems
Secondary Predicate 510(k): K112102

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. It is for prescription use in a home or healthcare facility and is used by physicians and polysomnographic (PSG) technologists as a support tool to aid in the evaluation and diagnosis of sleep disorders. A PSG tecnologist must edit, score, and review the data before sleep reports are generated.

The Cerebra Sleep System is capable of collecting data required for Level 2 PSG and Level 3 HSAT studies. A Level 3 HSAT study is a home sleep apnea test with a minimum of 4 channels that include oxygen saturation, electrocardiogram (ECG) or heart rate, airflow (e.g., nasal flow), and respiratory effort (e.g., chest band). A Level 2 PSG study is an unattended sleep test with a minimum of 7 channels that include electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG) or heart rate, chin electromyogram (EMG), and all signals from Level 3.

The Cerebra Sleep System (CSS) is comprised of three main areas:

- Prodigy: This is a PSG recorder capable of performing Level 2 and Level 3 sleep studies. It includes the Head Mounted Unit (HMU), which is worn on the patient's head, the Chest Mounted Unit (CMU), which is affixed to a chest effort belt, the Table Top Unit (TTU), which receives data wirelessly, and third party accessories including an oximeter.
- Cerebra Analytics Suite (CAS): The CAS has 4 components - Web Processing (for signal processing of data), Web Scoring (for generating scoring results, which encompasses autoscoring), Cerebra Viewer (for viewing and editing PSG studies and scoring results) and Web Reporting (for generating reports). A PSG technician must edit, score, and review the data before reports are generated. These components utilize well-defined file formats to enable communication; communication with each component is done through the internet, via the Cerebra Portal.
- Cerebra Portal: All areas of the CSS product are managed by the Portal software. The Portal is used to configure a study on the TTU and allows sleep analysis service providers to manage inventory, patients, and sleep studies. It also configures Prodigy system hardware for an individual sleep study to be performed by a patient.

V. INDICATIONS FOR USE

The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration. The Cerebra Sleep System is for prescription use in a home or healthcare facility.

The Cerebra Sleep System is intended to be used as a support tool by physicians and PSG technologists to aid in the evaluation and diagnosis of sleep disorders. It is intended to provide sleep-related information that is interpreted by a qualified physician to render findings and/or diagnosis, but it does not directly generate a diagnosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate devices in order to demonstrate substantial equivalence:

Table 1: Comparison of Cerebra Sleep System with primary predicate device (K152040).

	Cerebra Sleep System	**X8 System (K152040)**
Product Code	OMC, OLV, OLZ	OMC, OLV
Regulation	Same as predicate.	21 CFR 882.1400 Electroencephalograph An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.
Indications for Use	The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration. The Cerebra Sleep System is for prescription use in a home or healthcare facility. The Cerebra Sleep System is intended to be used as a support tool by physicians and PSG technologists to aid in the evaluation and diagnosis of sleep disorders. It is intended to provide sleep-related information that is interpreted by a qualified physician to render findings and/or diagnosis, but it does not directly generate a diagnosis.	The X8 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit, and display physiological signals from adult patients. All X8 models (SP40, SP29, and XS29) acquire, record, transmit, and/or display electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals. Model SP29 additionally includes a nasal pressure transducer and cannula (for airflow), thoracic and abdomen respiratory effort, and pulse rate and oxyhemoglobin saturation from the finger. The X8 system only acquires and displays physiological signals; no claims are being made for analysis of the acquired signals with respect to the accuracy, precision, and reliability.”
Patient Population	Same as predicate.	Adults
Anatomical Sites	Forehead, Head, Chest, Abdomen, Chin, Legs and Finger	Forehead, Head, Chest, Abdomen, Chin and Finger

Environment of Use	Home (data acquisition), Healthcare facility (data acquisition, analysis and reporting)	Home (data acquisition), Healthcare facility (data acquisition, analysis and reporting), Clinical Research Environment
User Control	ON/OFF – Tablet End Study	ON/OFF
Visual Indicator	Blue, Green, Yellow, Red Light Pipe.	Green and yellow LED
Audio Indicator	None	Speaker. Voice messages alert user to problems during recording.
EEG Electrodes	Ambu 720 Series AM-72000S/E (K970639)	Vermed VersaTrode Sensor 40- 4305 (K781430)
EOG Electrodes	King Lead, Touch Proof, Single Snap, KM-S020, (HC 99983) Ambu 720 Series AM-72000S/E (K970639)	Vermed VersaTrode Sensor 40- 4305 (K781430)
ECG Electrodes	King Lead, Touch Proof, Single Snap, KM-S020, (HC 99983) Ambu 720 Series AM-72000S/E (K970639)	Vermed VersaTrode Sensor 40-4305 (K781430)
EMG Electrodes	King Lead, Touch Proof, Single Snap, KM-S021, (HC 99983) King Lead, Touch Proof, Single Snap, KM-S022, (HC 99983) King Lead, Touch Proof, Single Snap, KM-S008, (HC 99983) Ambu 720 Series AM-72000S/E, (K970639) Natus 019-429400 (K850108) Kendall CV-31112/E (Exempt)	Vermed NeuroPlus Sensors A10041-60 (K010638)
Linked Mastoid Sensors	King Lead, Touch Proof, Single Snap, KM-S011, (HC 99983) Ambu 720 Series AM-72000S/E, (K970639)	MBS (3BF3) Disposable Ag/Cl sensors with adhesive (K842514)
Respiratory Accessory	Same as predicate.	Nasal Cannula and nasal pressure sensor Chest and abdomen effort belts
Signals Acquired	• Forehead/head EEG • Infra-red (IR) and red optical signal • Acoustic microphone • 3-D Actigraphy • Optional channel • (ECG/EEG/EOG/EMG) • Nasal Pressure & cannula (airflow) • Respiratory Effort	• Forehead/head EEG • Infra-red (IR) optical signal • Acoustic microphone • 3-D actigraphy • Optional channel • (ECG/EEG/EOG/EMG) • Nasal Pressure & cannula (airflow) • Respiratory Effort • Photoplethysmography
Power Supply	TTU: Non-removable min. 3000 mAH Li-ION HMU/ CMU: Non-removable 800 mAH 3.7V Li-Po batteries	1 x 600 mAH 3.7V Li-ION battery
Battery Charging	Patients &Technicians - Via USB cable connected to USB port or USB wall charger	Patients - external battery pack Technicians - Via USB cable connected to USB port or USB wall charger
Typical Charging Time	Same as predicate.	0.5 – 3.0 hours
Acquisition modes	Record	Record or Monitor
Operating Time	Hours of Use: 0-4 days after charging: Record: 9 to 13Hrs	Hours of Use: 0-4 days after charging: Record: 11.5 – 18.5

	5–10 Days after charging: Record: 8 to 10 Hrs	5-10 days after charging: Record: 10.0 - 16.5
Data Storage	32 GB Tablet Storage min.	8 GB Micro-SDHC memory card or greater capacity
File size per 8 hr recording	Approx: 120MB	Standard mode – 72 MB PSG2 Mode – 134 MB
Dimensions	Table Top Unit (TTU): ~21 x 12 x 0.7 cm Head-Mounted Unit (HMU): ~63 x 38 x 28 cm Chest-Mounted Unit (CMU): ~140 x 36 x 24 cm	2.1" long, 1.5" wide, 0.75" deep
Weight	TTU: ~300 g (~10 ounces); HMU: ~56 g (~2.0 ounces) CMU: ~81 g (~3 ounces)	2.5 ounces with battery
Cleaning enclosures and EEG Strip	Cleaned and disinfected by: Pre-clean using solution with a minimum Hydrogen Peroxide concentration 0.5% w/w or 10% aqueous sodium hypochlorite solution and allow the device to remain wet for minimum 3 minutes. Repeat to disinfect; place devices in a clean dry area to prevent re-contamination.	Cleaned and disinfected by rubbing with alcohol-based hand sanitizer and isopropyl alcohol.
Cleaning enclosure strap	Same as predicate.	Cleaned and disinfected by washing with dish soap.
Nasal Pressure Transducer	Pressure transducer luer incorporated on CMU device to attach Nasal cannula.	Pressure transducer incorporated into airflow adapter, Affixes to USB connector Size: 3.5 (l) x 2.5 (w) x 1.5 (d) cm Weight - 5.5 grams
Oximeter	Same as predicate.	Bluetooth (BT) used to obtain pulse and SpO2 acquired with wrist oximeter. Nonin WristOx2 Wireless Pulse Oximeter (K102350)
Respiratory effort belts	Uses 3rd party respiratory induced plethysmography (RIP) thorax and abdomen effort belt - SleepSense (K042253)	Uses 3rd party respiratory induced plethysmography (RIP) thorax and abdomen effort belts Philips/Pro-Tech ezRIP Respiratory Effort Sensors (K913395), and Ambu SleepMate RIPmate Respiratory Effort Sensor (K903300)
Data transfer	No Physical transfer	Native *from SD card* through USB
Study Setup	Devices are set up via Cerebra Portal. Devices must be connected to Wi-Fi or cellular to set up the device for a sleep study.	Devices are Setup via Device Manager. Devices must be connected to PC via USB in order to Setup the device for a sleep study.
Device/Inventory Management	Devices and serial numbers of devices are stored in Cerebra Portal. Technicians select the serial number from the list of devices in inventory when setting up a study. Cerebra Portal displays devices that are assigned to a study or that are in stock and available to be assigned to a study	Device serial number is only displayed when the device is connected via USB. Inventory management is handled manually, not as part of the Device Management
Portal Access	Same as predicate.	Technicians receive email invitation with a link to create their password for their account. Technicians have a username and password to login to the Portal
USB data transfer rate	Not Applicable	> 250 MB per minute
Wireless data transfer	Bluetooth; WiFi; Cellular	Bluetooth

Maximum Bluetooth wireless transfer distance and rate	Same as predicate.	Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud
Compatibility	Personal computer with 2.4GHz (Pentium 4) processor or better, 2 GB RAM or higher (or equivalent). Windows 10 or Mac iOS Operating System Microsoft Edge, Google Chrome, Apple Safari or Firefox Internet connection required	Personal computer with 2.4GHz (Pentium 4) Processor or better, 2 GB RAM or higher (or equivalent) with Windows 7, 8, or Mac iOS Operating System
Estimated file size per minute	Up to 355 KB/Min depending on configuration	Standard Mode: 150 KB/Min PSG2 Mode: 280 KB/Min
File format type	European Data Format (EDF), converted from Cerebra Sleep Data (CSD) and Cerebra Channel Data (CCD).	European Data Format (EDF)
Presents raw signals during acquisition in monitoring mode	N/A	Yes
Presents previously acquired signals	Same as predicate.	No
Desktop interface min. computer requirements	Not applicable for Prodigy or Cerebra Portal	1. Processor : 2.4 GHz; 2. Operating System: Windows 7 or 8; 3. RAM: 2GB; 4. USB port: 1
Web interface minimum computer requirements	1. Processor: Minimum 2.4 GHz; 2. Operating System: Windows 10, Mac iOS; 3. No Java dependency (HTML/JS only); 4. RAM: 1GB; 5. No USB port is required; 6. Internet connection: constant; 7. Browser: Microsoft Edge, Google Chrome, Apple Safari, or Firefox	1. Processor : Minimum 2.4 GHz; 2. Operating System: Windows 7 or 8, Mac iOS; 3. Java version 6 or greater; 4. RAM: 1GB; 5. USB port: 1; 6. Internet connection: constant; 7. Browser: Internet Explorer, Firefox, Opera, Chrome, or Safari
Web interface server requirements.	Virtual Server: 1. Processing: Google Cloud; 2. Operating system: any O/S supporting Docker; 2. Certificates: Signed SSL; 3. Application framework: Rails 6.0 & .NET Core 2.1; 4. Database: Google Cloud SQL, Google Cloud Storage Physical Server – not applicable	Virtual Server: 1. Processor: > 2 GHz; 2. Operating system: WinServer 2008. 3. RAM: > 2GB; 4. Certificates: Signed SSL; 5. .NET framework: version 2.0 – web server version 3.5 – processing server or Win Server 2008 6. Database: SQL server 2005 Physical Server: 1. Processor: > 2 GHz; 2. Operating system: Win Server 2008 Enterprise edition (for virtual servers); 3. RAM: > 2GB
Computer/portal Security	• Installation requires administrative rights to Cerebra Google Cloud. • User must have rights to the account to access data via the Portal. No group access, each User access is defined according to role & associated permissions. • No requirement to directly manage the firewall.	1. The person installing the Java applet must have administrator privileges. 2. User must have rights to the account and group to access data via the portal. 3. The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39.

	• Industry standard access management: HTTP authentication over SSL, token authentication for TTU. Portal uses Device Gem (Rails 6.0) • Data in test and development environments is anonymized. Administrative access in Production is limited to required staff. Source code and database access limited to required development staff. Access to testing system (Jenkins) restricted to internal VPN.	
Benchtop Performance Testing	• ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 + A2:2010 and CAN/CSA-C22.2 No. 60601-1:14 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2014 (4th Edition) Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests • IEC 60601-1-2:2020 (4.1 Edition) Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests • ANSI/AAMI HA60601-1-11:2015 and CAN/CSA-C22.2 No. 60601-1-11:2015 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment • IEC 60601-2-26:2012 Particular requirements for the basic safety and essential performance of electroencephalographs • AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems • ANSI / IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence • IEC 62133-2: 2017 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 • ISO 14971:2007 and 2012 Medical devices - Application of risk management to medical devices	• IEC 60601-1:2005 (3rd Edition) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2:2014 (4th Edition) Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests • IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment • IEC 60601-2-26:2012 Particular requirements for the basic safety and essential performance of electroencephalographs • 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 • ISO 14971:2007 Medical devices - Application of risk management to medical devices

Clinical Testing	Clinical testing compared device's results with those obtained using commercial PSG equipment available in 3 sites	Advanced Brain Monitoring has conducted prospective studies to compare equivalence of signals obtained with X8 System airflow and respiratory effort signals with an FDA cleared device, Compumedics Somte (K072201)
Biocompatibility	Testing on patient-contacting materials: • ISO 10993-5: 2009 Cytotoxicity; ISO 10993-10: 2010 Sensitization; ISO 10993-10: 2010 Irritation	Not available.
Cleaning Validation	Reprocessing protocols. Verify reprocessing (i.e. cleaning and disinfecting) instructions intended to be included in device labeling does not contribute to deterioration of mechanical components. Used FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". Per Section VI of document, device is considered a "Non-Critical Device" as it is intended to contact only intact skin and is not intended to penetrate it.	Not available.
Sterilization	N/A	N/A
Usability	Cerebra Medical Ltd. has conducted usability testing, as per IEC 62366:2015 Medical Device Usability Engineering standard, to evaluate the performance and usability of the system.	Advanced Brain Monitoring has conducted usability testing to demonstrate that high quality signals can be obtained when the X8 System is self-applied with the user instructions. X8 System Model SP29 was used for both portions of the study.

Table 2: Comparison of Cerebra Sleep System with secondary predicate device (K112102).

	Cerebra Sleep System	**Michele Sleep Scoring System (K112102)**
Product Code	OMC, OLV, OLZ	MNR
Regulation	21 CFR 882.1400 Electroencephalograph An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.	21 CFR 868.2375 Breathing frequency monitor A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits. This device does not include the apnea monitor classified in § 868.2377.

Indications for Use	The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration. The Cerebra Sleep System is for prescription use in a home or healthcare facility. The Cerebra Sleep System is intended to be used as a support tool by physicians and PSG technologists to aid in the evaluation and diagnosis of sleep disorders. It is intended to provide sleep-related information that is interpreted by a qualified physician to render findings and/or diagnosis, but it does not directly generate a diagnosis.	The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders. The MICHELE Sleep Scoring System is intended to be used for analysis (automatic scoring and manual rescoring), display, redisplay (retrieve), summarize, reports generation and networking of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. The device is to be used under the supervision of a physician. Use is restricted to files obtained from adult patients
Clinical condition or purpose	Diagnosis of sleep disorders.	Diagnosis of sleep and respiratory disorders.
Population: Human subjects undergoing sleep studies	Same as predicate.	Yes
Five-stage Sleep Stage Scoring (wake, Rem, three non-Rem stages)	Same as predicate.	Yes
Arousal Scoring	Same as predicate.	Yes
Respiratory Events Scoring	Same as predicate.	Yes
Leg Movements Scoring	Same as predicate.	Yes
Processing of PSG recorded from patients and PSG report creation	Same as predicate.	Yes
Central EEG	Same as predicate.	Scoring; display; reporting

Left and right eye EOG	Same as predicate.	Scoring; display; reporting
Chin EMG	Same as predicate.	Scoring; display; reporting
ECG	Same as predicate.	Scoring; display; reporting
Chest and abdomen respiratory	Same as predicate.	Scoring; display; reporting
Oxygen saturation	Same as predicate.	Scoring; display; reporting
Respiratory airflow	Same as predicate.	Scoring; display; reporting
Thermister	Scoring	Scoring; display; reporting
Audio	Same as predicate.	Scoring; display; reporting
Head/Body position	Same as predicate.	Scoring; display; reporting
Airway CO2	Scoring	Scoring; display; reporting
Airway pressure	Scoring	Scoring; display; reporting
EMG recorded from right and left legs	Same as predicate.	Scoring; display; reporting
PSG records scored per 30 second epoch	Same as predicate.	Yes
Cardiac artifacts removed from EEG, EMG and ECG	Same as predicate.	Yes
Support multiple Config/Study Types	Same as predicate.	Yes
Desktop interface minimum computer requirements	Cerebra Portal and most of Cerebra Analytics Suite: Not applicable CAS Cerebra Viewer: 1. Processor: 2.0 GHz or faster; 2. Operating System: Windows 10 64 bit; 3. RAM: 4GB; 4. Monitor: 19 inch or greater; 1600 x 1050 resolution	1. Processor : 1.6 GHz 2. Operating System: Windows 10 3. RAM: 4GB 4. Monitor: 19 inch or greater; 1280 x 1024 resolution
Usability Testing	Same as predicate.	Usability testing was conducted for the product.
Clinical Testing	Same as predicate	Validation testing included comparison of autoscoring to those obtained by manual scoring.

VII. PERFORMANCE DATA

The following performance data were provided in support of the safety and efficacy of the subject device, as well as support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Sterilization is not applicable to this device. Instead, cleaning and disinfection are applicable to the reusable components.

Shelf-life is only applicable to the rechargeable polymer lithium-ion batteries used in the system. Appropriate shelf-life testing was conducted for the battery components in the Cerebra Sleep System. The batteries passed this testing.

Biocompatibility Testing

The following biocompatibility testing was provided to demonstrate the safety and efficacy of the Cerebra Sleep System:

- ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

The device passed all biocompatibility testing per the test standards.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

The following electrical safety and EMC testing were provided to demonstrate the safety and efficacy of the subject device, as well as substantial equivalence with the predicate:

- ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 + A2:2010 and CAN/CSA-C22.2 No. 60601-1:14 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI HA60601-1-11:2015 and CAN/CSA-C22.2 No. 60601-1-11:2015 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2:2014 and :2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-26:2012 and CAN/CSA-C22.2 No. 60601-2-26:14 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 60601-2-49:2011 and CAN/CSA-C22.2 No. 60601-2-49:11 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.
- AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
- ANSI / IEEE C63.27:2017 American National Standard for Evaluation of Wireless Coexistence

The device passed all electrical safety and EMC testing per the test standards.

Software Verification and Validation Testing

Software verification and validation testing in compliance with IEC 62304:2006 were provided to demonstrate the safety and efficacy of the subject device. Testing was conducted and documented as per the recommendations in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The Cerebra Sleep System has been thoroughly tested through hundreds of test cases of various types (unit, integration, exploratory, system, regression, usability, etc.). The results of these activities demonstrate that the software meets requirements for safety, function, and intended use.

Software Verification and Validation Testing - Autoscoring

For the autoscoring module of the Cerebra Sleep System, a validation study was performed to demonstrate the safety and effectiveness of the software and to support substantial equivalence to the predicate Michele Sleep System. The testing consisted of comparing the autoscoring software with the current gold standard (manual scoring) for key sleep variables. The sleep dataset consisted of 138 randomly selected pre-existing sleep studies from both sleep laboratory (Level 1 sleep test) and in-home (Level 2 or 3 sleep test) use environments.

Sleep recordings were manually scored by three board-certified registered polysomnographic technologists (RPSGT) who had a minimum of 13 years of experience scoring sleep studies. The technicians followed the rules outlined in the American Academy of Sleep Medicine manual for the scoring of sleep and associated events.

When comparing the Cerebra Sleep System (CSS) autoscoring software to the consensus manual scoring, the results showed moderate to substantial agreement, as reported in Table 3.

Table 3 - Comparison of CSS autoscoring to consensus manual scoring in all studies

	CSS Autoscoring				
Scoring Function	Total Epochs by Techs	APPA	ANPA	Overall % Agreement	Kappa
SLEEP STAGING	114017			79.90	0.72
Awake	28838	82.32	97.15		
N1	11242	56.80	91.64		
N2	48806	82.95	88.05		
N3	10442	84.51	97.16		
REM	14689	79.41	98.84		
No Consensus	1654				
AROUSALS	81526			86.36	0.48
Yes	11043	64.79	89.74		
None	70483				
PLMs	81526			95.99	0.69
Yes	6315	64.96	98.59		

None	75211				
RESPIRATORY EVENTS	81526			89.18	0.54
Overall Apneas	5631	62.60	93.03		
Hypopneas & RERAs	3608	66.52	98.65		
None	72287	92.38	73.11		
No Consensus	833				

Note: Numbers in sleep staging rows are number of 30-second epochs. Event rows are the number of epochs where an event began except in the "None" category where the number refers to number of epochs with no events. APPA = Averaged Positive Percent Agreement; ANPA= Averaged Negative Percent Agreement; N1, N2, and N3, REM are sleep stages; PLMs = periodic limb movements; RERAs = respiratory effort-related arousals; No Consensus = all three technologists gave different scores.

Cerebra Sleep System was also accurate for classifying sleep scoring stages of wake (82.3%), N1 (56.8%), N2 (83.0%), N3 (84.5%), and REM (79.4%), see Table 4.

Table 4 – Confusion matrix comparing the classification of sleep stages of the CSS autoscoring (Automatic Analysis) with the consensus of three manual scorers (Manual Staging).

		Automatic Analysis					
		Wake	N1	N2	N3	REM	Epoch Count
Manual Staging	Wake	**82.3%**	10.4%	4.5%	1.4%	1.3%	28838
	N1	9.7%	**56.8%**	30.7%	0.3%	2.5%	11242
	N2	1.6%	9.4%	**83.0%**	5.1%	1.0%	48806
	N3	0.5%	0.2%	14.6%	**84.5%**	0.2%	10442
	REM	3.3%	7.0%	10.3%	0.1%	**79.4%**	14689

A similar performance analysis was completed for the Michele Sleep System autoscoring and the Alice 5 autoscoring, where the two autoscoring software systems were compared to consensus manual scoring. The results, as per Table 5, show that the Cerebra Sleep System autoscoring performance is similar to the Michele software performance and far exceeds the Alice 5 software performance. Although the CSS autoscoring was run on a different dataset than the Michele and Alice 5, the CSS autoscoring shows a similar and appropriate agreement with manual scoring.

Table 5 - Comparison of CSS autoscoring performance to Michele and Alice 5 reported results

	Latest Autoscoring		Michele		Alice 5	
Scoring Function	Overall % Agreement	Kappa	Overall % Agreement	Kappa	Overall % Agreement	Kappa
Sleep Staging	79.9	0.72	82.6	0.77	30.5	0.06
Arousals	86.4	0.48	89.9	0.54	57.9	0.10
PLM Index	96.0	0.69	95.7	0.69	88.3	0.38
Respiratory Events	89.2	0.54	94.0	0.74	78.0	0.25

Benchtop Performance Testing

The following benchtop performance testing was provided to demonstrate substantial equivalence with the predicate device:

- Human Factors / usability testing in accordance with IEC 62366-1:2015
- Cleaning Validation
- Hardware inspections
- Mechanical verification and inspection
- Shipping validation per ASTM D4169

The devices passed all benchtop performance testing per the testing requirements.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Performance Testing

Clinical validation was prospectively conducted to demonstrate the safety and effectiveness of the device. The aim of the validation was to demonstrate that the signals obtained by the Cerebra Sleep System are comparable to those obtained with in-laboratory Level 1 PSG signal acquisition systems. Key comparisons between manually scored total sleep time (TST), the apnea hypopnea index (AHI), respiratory disturbance index (RDI), sleep onset latency, sleep stages, sleep onset latency, and the periodic limb movement index (PLMI) derived from the Cerebra Sleep System and two types of Level 1 systems (Philips Respironics Alice 6, K040595; Nihon Kohden PSG-1100, K120888) from three different sites was performed to show statistical equivalence between the measurements. Eighty-four participants were part of the validation, with sample characteristics (Age: 46.7±13.6, BMI: 34.5±9.0, Sex: 48.8% Male, Ethnicity: 75% White) that are similar to patients attending sleep disorder clinics.

All objectives for the validation were fulfilled. There were no statistically significant differences of the measured sleep variables in the overall sample or in two out of the three sites. The validation therefore showed that the signals generated by the Cerebra Sleep System are comparable to those generated by the commercial in-laboratory Level 1 data acquisition systems.

VIII. CONCLUSIONS

Cerebra Medical considers the Cerebra Sleep System to be substantially equivalent to the predicate devices in terms of indications for use, technological characteristics and testing performed.