November 19, 2024

Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K242930
Trade/Device Name: Natus BrainWatch System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: November 12, 2024
Received: November 12, 2024

Dear Prithul Bom:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Natus BrainWatch System (Natus BrainWatch System)

Indications for Use *(Describe)*

The Natus BrainWatch System including the Natus BrainWatch Headband, is intended to record and store EEG signals and present these signals visually to assist trained medical staff in making neurological diagnoses in patients aged 2 years and older.

The device does not provide any diagnostic conclusions about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Natus BrainWatch System is intended for use within a professional healthcare facility or clinical research environment. The Natus BrainWatch Headband is intended for single-patient use.

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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510K Summary

Date: November 5, 2024

Submitted by: Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
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Canada L6H 5S1

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Proprietary Name: Natus BrainWatch™ System

Common Name: Electroencephalograph

Regulation Number: 21 CFR 882.1400

Classification Name: Reduced montage standard electroencephalograph

Product code: OMC, GXY

Device Class: II

Predicate Device: Ceribell Pocket EEG Device (K170363), Ceribell Instant EEG Headband (K210805)

Description:

Overview: Natus BrainWatch System

The Natus BrainWatch system is a reliable, mobile, and easy-to-use EEG device intended to record, store, and visually present EEG signals to assist trained medical staff in making neurological diagnoses in patients.

The system includes a touchscreen tablet as its primary interface. The Natus BrainWatch Headband is a single-use disposable headpiece with an integrated array of 10 passive electrodes that are applied to the patient's head to record EEG signals when connected to an amplifier.

The Natus BrainWatch System consists of the following components: Tablet, IV Pole Handle, Amplifier, Headband(s), Gel Pods and a Mobile Application:

- Touchscreen Tablet with charger
- Single-Use disposable elastic fabric headband with 10 electrodes (available in sizes Small, Medium, and Large) containing:
  - Hydroflex patch with 2 built-in electrodes
  - 8 electrodes attached to gel pods used to improve impedance levels labeled L1-L4, R1-R4
- Wireless amplifier that attaches to the headband and connects to the tablet via Bluetooth™
- IV pole handle that holds the tablet for a hands-free experience
- Gels pods attach to the electrodes to improve impedance levels

The Natus BrainWatch System is a portable 10-channel EEG monitoring system. 10 patient electrodes are used to record the 10 channels. Channels 1-5 should be used for the patient's left hemisphere, with channel 1 at the front of the patient's head and channel 5 at the back. Channels 6-10 should be used for the patient's right hemisphere, with channel 6 at the front of the patient's head and channel 10 at the back.

EEG recording files are transferred wirelessly to a computer from the Natus BrainWatch Tablet using a Wi-Fi connection. The EEG sessions from Natus BrainWatch are stored using a cloud-based solution which allows the end user to view studies at a later date. Recorded sessions can be reviewed remotely on a computer using the Neuroworks ® EEG software.

Note: The network must support WiFi Protected Access (WPA/WPA2) security.

Operating Principle of Natus BrainWatch System

The device is a portable, 10-channel EEG monitoring system. The device connects to a headband consisting of 10 patient electrodes which are used to form the 10 channels and may be used with any scalp EEG electrodes.

The system acquires the EEG signals of a patient and presents the EEG signals in visual formats in real time. The EEG recordings are displayed on a computer or tablet using an EEG viewer software. The visual signals assist trained medical staff to make neurological diagnoses. It does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event.

Micro-USB cable is used to connect the Natus BrainWatch System to power adapter for charging. Bluetooth is used to connect amplifier with tablet to transfer EEG recording files. When the Natus BrainWatch System is connected to a power adapter of a computer, all EEG acquisition functions are automatically disabled.

Natus BrainWatch System Features

- Rapid Setup: The Natus BrainWatch system can be set up quickly, typically within minutes.
- Portability: The device features an integrated electrode headband and a compact amplifier that connects wirelessly to a tablet, ensuring high portability and convenience for bedside use.

System Setup Overview

The Natus BrainWatch System setup involves several steps to ensure proper operation and accurate data capture. First, power on the tablet, followed by turning on the amplifier. Connect the amplifier to the tablet via Bluetooth. Prepare the amplifier and headband by attaching the amplifier to the headband and placing the headband on the patient's head. Adjust the electrodes until the green light is displayed on the Electrode Page, indicating proper electrode placement. Enter patient demographic information into the system to ensure accurate data association. Once setup is complete, the system is ready for recording and monitoring EEG signals. When finished, stop the recording to conclude the session.

Device-patient interaction Accessories List:

The Headband will be in contact with the hair and skin of the patient's head throughout the study.

Accessories:

Item	Model Number
Hanger Assembly (Tablet Hanger)	045276
Carry Case	046863

Indications for Use

The Natus BrainWatch System including the Natus BrainWatch Headband, is intended to record and store EEG signals and present these signals visually to assist trained medical staff in making neurological diagnoses in patients aged 2 years and older.

The device does not provide any diagnostic conclusions about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Natus BrainWatch System is intended for use within a professional healthcare facility. The Natus BrainWatch Headband is intended for single-patient use.

Comparison to the Predicate Device:

There are 2 predicates: Ceribell Pocket EEG Device (K170363) and Ceribell Instant EEG Headband (K210805)

There is one reference device; CGX Quick (K203331) which is used for referring wireless amplifier technology. Both the subject device and the reference device use Bluetooth 5.9 technology.

The SE comparison table below is provided to compare the similarities and differences in the indications for use (intended use environment, intended use population) and the technological characteristics of the subject device and the predicates.

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
Device Class	Class II	Class II	Class II	Same as predicate
Device Code	OMC, GXY	OMC	GXY	Same as predicate

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
Class Name	Reduced montage standard electroencephalograph, Cutaneous Electrode	Reduced montage standard electroencephalograph,	Cutaneous electrode	Same as predicate
Classifying Regulation	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.1320	Same as Predicate
Indications for Use	The BrainWatch System including the BrainWatch Headband, is intended to record and store EEG signals and present these signals visually to assist trained medical staff in making neurological diagnoses in patients aged 2 years and older. The device does not provide any diagnostic conclusions about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Natus BrainWatch System is intended for use within a professional healthcare facility. The Natus BrainWatch Headband	The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and does not provide. any automated alerts of an adverse clinical event. The Pocket EEG Device is intended to be used in a professional healthcare facility environment.	The Ceribell Instant EEG Headband is an electroencephalogram (EEG) electrode array intended for single patient use in the recording of EEGs in patients of 2 years and older. The Instant EEG Headband is intended for prescription use in the home, healthcare facility, or clinical research	Similar to predicate but equivalent in safety and effectiveness The subject device indications for use statement is more descriptive and clearer. The clinical purpose of the predicate and subject devices is same.

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
	is intended for single-patient use.			
Where used	Professional healthcare facility.	Professional healthcare facility	Professional healthcare facility, in the home or clinical research	Same as predicate
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same as predicate
DC Channel	All (10) channels are referential	8 Differential only	N/A	Similar to predicate but equivalent in safety and effectiveness. Identical electrode numbers and contact positions. Equivalent or better in effectiveness, as the subject device can capture either 10 channels of referential signals or 8 channels of differential signals.
A/D Conversion	24-Bit Delta-Sigma	24-Bit Delta-Sigma	N/A	Same as predicate

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
Sampling Rate	250 Hz	250 Hz	N/A	Same as predicate
Battery charging power adapter	100-240V AC power adapter	100-240V AC power adapter	N/A	Same as predicate
Bedside Unit-PC Interface	Bedside unit to computer using WiFi	Bedside unit to computer using WiFi or Micro-USB cable	N/A	Similar to predicate but equivalent in safety and effectiveness. Predicate device has a Micro-USB cable as an alternate option.
WiFi frequency/standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n	N/A	Same as predicate
Type of Applied Part	BF	BF	N/A	Same as predicate
Type of Patient Contact	Contacts patient scalp	N/A	Contacts patient scalp	Same as predicate
Type of Use	Single use, non-sterile, disposable	N/A	Single use, non-sterile, disposable	Same as predicate
Available Sizes	Small 45-51 cm Medium 50-56 cm Large 55-62 cm	N/A	Small 45-51 cm Medium 50-56 cm Large 55-62 cm	Same as predicate
Number of Electrodes	12 (Locations: Fp1, F7, T3,T5, O1, Fp2, F8, T4, T6, O2, Reference, Ground)	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	Similar to predicate but equivalent in safety and effectiveness.

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
				The subject device has 12 electrodes compared to 10 electrodes on the predicate device. The locations are identical according to the 10-20 system, with the reference and ground being the 2 additional electrodes.
Type of Electrodes	Passive Ag/AgCl	N/A	Passive Ag/AgCl	Same as predicate
Conductive Electrolyte Gel	Conductive electrolyte gel is included in sealed gel pods integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using another gel pod.	N/A	Conductive electrolyte gel is included in sealed gel packets integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	Similar to predicate but equivalent in safety and effectiveness. To add additional gel to the subject device, a new, fully filled gel pod can be replaced. For the predicate device, additional gel is applied using a syringe.

Feature	Subject Device Natus BrainWatch Sytem	Predicate 1 Ceribell Pocket EEG Device, K170363	Predicate 2 Ceribell Instant EEG HeadbandK210805	Comments
				Subject device and predicate device use conductive electrolyte gel to form an electrical connection between the patient scalp and the Ag/AgCl electrodes.
Biocompatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization and Cytotoxicity testing per ISO 10993-5:2009, ISO 10993-23:2021 and ISO 10993-10:2021	Biocompatibility of patient contacting components verified with Irritation, Sensitization and Cytotoxicity testing per testing per ISO 10993-5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Irritation, Sensitization and Cytotoxicity testing per testing per ISO 10993-5:2009 and ISO 10993-10:2010	Similar to predicate but equivalent to safety and effectiveness. Testing was performed to current standards.

Reference device for wireless amplifier technology:

Feature	Subject Device Natus BrainWatch System	Reference Device CGX Quick-20m (K203331)
Device Class	Class II	Class II
Device Code	OMC, GXY	GWL, GXY
Class Name	Reduced montage standard electroencephalograph, Cutaneous Electrode	Physiological Signal Amplifier
Classifying Regulation	21 CFR 882.1400, 21 CFR 882.1320	21 CFR 882.1835, 21 CFR 882.1320
Wireless	Amplifier to Tablet using Bluetooth 5.0	Amplifier to receiver (PC) using Bluetooth 5.0

Subject device is similar to Reference device but equivalent to safety and effectiveness. The Subject device and Reference device both use Bluetooth 5.0 technology. While the specific modules may differ in aspects such as power consumption, antenna design, or firmware capabilities, these differences are minor and do not impact the overall performance or safety of the devices.

The Subject device has been tested and certified under FCC Part 15 regulations. Additionally, the Subject device has undergone EMC compliance testing per IEC 60601-1-2 and Wireless Coexistence testing per ANSI C63.27-2021. These tests ensure that the Subject device's wireless amplifier does not interfere with other electronic devices and can coexist with them in a typical medical environment.

The Natus BrainWatch System and its predicates are substantially equivalent in features and technical characteristics. There are no major differences that significantly alter the intended use or raise new issues of safety or effectiveness.

Brief Summary of Performance Testing

Electrical Safety

The Natus BrainWatch System was verified for performance in accordance with the following standard:

- IEC 60601-1-6:2010/AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EC 60601-1:2005/AMD2:2020- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 80601-2-26: 2019- Particular requirements for the basic safety and essential performance of electroencephalographs

Electromagnetic Compatibility

The Natus BrainWatch System was verified for performance in accordance with the following standard:

- IEC 60601-1-2 Ed 4.1 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic Disturbances – Requirements and tests.

Packaging and Handling Verification

The packaged Natus BrainWatch System components have successfully passed packaging and handling verification as per ASTM D4169-22

Performance Testing – Bench Verification & Validation

The Natus BrainWatch System has successfully passed performance verification and validation in accordance with internal requirements and specifications at the system level.

The Bench testing verification and validation was performed to confirm device meets the functional and performance characteristics.

Additionally, Natus BrainWatch System has been tested and met defined acceptance criteria. The tests included:

- Requirements for the basic safety and essential performance of electroencephalographs per IEC 80601-2-26
- Electromagnetic Compatibility and Electrical Safety Testing performed to applicable requirements of IEC 60601-1 and IEC 60601-1-2
- Battery Safety Testing per IEC 62133
- Shipping/distribution and vibration testing per ASTM D4169-22
- Biocompatibility of patient contacting components verified with Cytotoxicity, Irritation, and Sensitization testing per ISO 10993-5:2009, ISO 10993-23:2021, and ISO 10993-10:2021
- Performance Criteria of FDA Guidance titled Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway, issued on August 14, 2020.
- Wireless Coexistence per ANSI C63.27-2021
- Shelf-life testing

Results indicate that the Natus BrainWatch System complies with its predetermined specifications and the applicable standards.

Conclusions

The intended use and technology of the Natus BrainWatch System is similar to that of the predicate devices Verification and Validation were performed to ensure no new questions of safety or effectiveness are raised. The results of these activities demonstrate that the Natus BrainWatch System is as safe, as effective, and performs as well as or better than the predicate device