



March 13, 2026

Zeto, Inc.  
% Ameera Roubi  
Regulatory Consultant  
Innolitics, LLC  
1101 W. 34th St. #550  
Austin, Texas 78705

Re: K260455  
Trade/Device Name: New Wave System  
Regulation Number: 21 CFR 882.1400  
Regulation Name: Electroencephalograph  
Regulatory Class: Class II  
Product Code: GWQ, GXY  
Dated: February 11, 2026  
Received: February 11, 2026

Dear Ms. Roubi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto: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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260455

?

Please provide the device trade name(s).

?

New Wave System

Please provide your Indications for Use below.

?

The New Wave system is intended for prescription use in an outpatient healthcare facility or home use to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The New Wave system acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), electrooculogram (EOG), electromyogram (EMG), orientation sensor data, photic sensor data, external trigger signals, and video. The system is only intended to be used for short-term recordings up to 2.5 hours.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Date Summary Prepared: February 11, 2026

### Contact Information


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### Device Information

Element	Information
Submission Type	Special 510(k) – Device Modification
Proprietary Name	New Wave System
Common Name	Full-montage standard electroencephalograph
Classification Name	Electroencephalograph
Regulation Number	21 CFR 882.1400
Regulatory Class	Class II
Product Code	GWQ, GXY
Review Panel	Neurology

### Predicate Device Information

Element	Information
Predicate Device Name	Flexset System
Predicate 510(k) Number	K233403

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Element	Information
Product Code	GWQ, GXY
Classification Regulation	21 CFR 882.1400
Regulatory Class	Class II
Relationship to Subject Device	Same intended use, same technological characteristics except for minor modifications suitable for a Special 510(k)

## Device Description

The New Wave System is intended to acquire, analyze, transmit, display and store primarily EEG and optionally auxiliary signals. The New Wave is designed to perform EEG using 19 signal electrodes and 1 dedicated active ground/driven-right-leg (DRL) electrode, adjusted and placed to comply with the 10-20 EEG system.

The device consists of the following components:


- Head Unit
- Electrodes
- Charger
- Display Unit
- Extension Unit
- Lead wires
- Software and Zeto Cloud Platform (ZCP)
  - Firmware and Display Unit software
  - Data center application
  - Client application

## Intended Use

The device is intended to measure, record, and display electrical activity of the brain for clinical evaluation and diagnosis of neurological conditions.

## Indications for Use

The New Wave system is intended for prescription use in an outpatient healthcare facility, or home use to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The New Wave system acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), electrooculogram (EOG), electromyogram (EMG), orientation sensor data, photic sensor data, external trigger signals, and video. The system is only intended to be used for short-term recordings up to 2.5 hours.

	<p style="text-align: center;"><b>510(k) Summary</b></p>	<p>New Wave System</p>
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## Contraindications for Use

The New Wave System is not intended for use in the following situations:

- Not intended for use in newborns
- Not intended for use in inpatient or hospital
- Not intended for recordings longer than 2.5 hours
- Not intended as a replacement for comprehensive neurological evaluation or diagnosis

## Substantial Equivalence Discussion

### Indications for Use Equivalence Discussion

The subject device, New Wave, retains the same overall intended use as the predicate Flexset system. Both devices are intended for prescription use to acquire, transmit, display, and store EEG and auxiliary physiological signals for adults and children, excluding newborns. The clinical purpose, patient population, and physiological measurements remain unchanged.

The differences between the indications relate only to the use environment and duration of recording. The New Wave is tailored for home, and outpatient healthcare facilities and short-term recordings up to 2.5 hours, whereas the predicate is cleared for use in a broader range of environments including healthcare facilities and transport. Flexset also supports longer monitoring durations to support the needs of the other use environments. These changes narrow the contexts in which the device may be used but do not expand the clinical purpose, user population, or diagnostic application.

Limiting the use environment and duration does not alter the underlying clinical use or introduce new clinical functions. Instead, these restrictions represent a subset of the predicate’s broader indications and therefore do not constitute a new intended use. Because the New Wave performs the same physiological measurements for the same population and clinical purpose as the predicate, and because its more limited indications remain fully encompassed within the predicate’s cleared intended use, the differences do not raise new questions of safety or effectiveness.

### Technological Characteristics Comparison

The Flexset System and the New Wave share the same fundamental technological characteristics across all core EEG acquisition and data management functions. Both devices use an identical 19-channel EEG electrode configuration with up to 8 auxiliary inputs, employ active dry Ag/AgCl electrodes (flat or bristle), and provide the same signal acquisition performance, including a 500 Hz sampling rate, 24-bit A/D conversion, and approximately 1  $\mu$ V RMS noise. Each system uses the same flexible, semi-rigid headset architecture designed to conform to

various head sizes while maintaining fixed electrode positioning consistent with the 10–20 EEG system. Wireless communication (Wi-Fi and LTE) and the firmware/software used for data acquisition, display, and analysis are also unchanged between the two devices.

The technological differences are minor and do not alter the device’s operating principles, performance, or data outputs. The New Wave’s narrower use environment does not affect the technological characteristics of the system and does not introduce new questions of safety or effectiveness.

## Device Comparison Tables

### Comparison- Overview

The following table provides a comparison of overview of the technological characteristics between the New Wave System and the Flexset System:

Feature/Function	New Wave	Flexset System (k233403)	Comments
System Components	<ul style="list-style-type: none"> <li>- Headset</li> <li>- Electrodes</li> <li>- Charger with cable</li> <li>- Display Unit</li> <li>- Extension Unit</li> <li>- Lead wires</li> <li>- Software:               <ul style="list-style-type: none"> <li>- Firmware and Display Unit Software</li> <li>- Data center application (same as K233403)</li> <li>- Client application (same as K233403)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Flexset (Headset)</li> <li>- Electrodes</li> <li>- Charger with cable</li> <li>- Display Unit</li> <li>- Extension Unit</li> <li>- Lead wires</li> <li>- Software:               <ul style="list-style-type: none"> <li>- Firmware and Display Unit Software</li> <li>- Data center application</li> <li>- Client application</li> </ul> </li> </ul>	Same
Signals Acquired	<ul style="list-style-type: none"> <li>- Scalp EEG</li> <li>- Orientation Sensor (accelerometer)</li> <li>- Optional non-EEG signals:               <ul style="list-style-type: none"> <li>- ECG</li> <li>- EOG</li> <li>- EMG</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Scalp EEG</li> <li>- Orientation Sensor (accelerometer)</li> <li>- Optional non-EEG signals:               <ul style="list-style-type: none"> <li>- ECG</li> <li>- EOG</li> <li>- EMG</li> </ul> </li> </ul>	Same



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	- Photic Trigger Detection - External Trigger Input - Video	- Photic Trigger Detection - External Trigger Input - Video	
Power Supply	1 × 5000 mAh 3.85V Lithium-Ion battery	1 × 3950 mAh 3.85V Lithium-Ion battery	The subject device has a slightly higher battery capacity, which supports its intended 2.5-hour operating time but does not change the underlying power supply technology or raise new questions of safety or effectiveness.
Battery Charging	Commercial grade wall charger	Medical grade wall charger	The subject device uses a commercial grade wall charger instead of a medical grade wall charger. Both charger types are designed to safely charge lithium-ion batteries and meet applicable electrical safety standards. The use of a commercial grade charger is appropriate for the subject device that implements medical device safety requirements as per IEC 60601-1 internally, without relying on the safety features of an external medical grade charger. This change does not



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			raise new questions of safety or effectiveness.
Typical Charging Time	0.5-3.5 hours	0.5-6.0 hours	The New Wave has a shorter typical charging time, consistent with its shorter operating time and intended use for short-term recordings.
Operating Time	2.5 hours	6-7 hours	The New Wave system has a shorter operating time of up to 2.5 hours compared to the predicate's 6-7 hours, reflecting its intended use in outpatient settings where only short-term recordings are required. This reduced duration aligns with the device's narrower indications for use and does not introduce new questions of safety or effectiveness.
Typical Use Duration	20 mins to 2.5 hours	20 mins to several hours	See discussion for operating time above.
Dimensions	Head Unit: a hemisphere with an approximate radius of 8 cm (3.1 in)  Display Unit: 22 cm × 9 cm × 2.2 cm (8.8 in × 3.5 in × 0.86 in)	Head Unit: a hemisphere with an approximate radius of 8 cm (3.1 in)  Display Unit: 22 cm × 9 cm × 2.2 cm (8.8 in × 3.5 in × 0.86 in)	Same

Weight	Head Unit: approx. 406 grams (14.3 ounces)	Head Unit: approx. 406 grams (14.3 ounces)	Same
	Display Unit: approx. 380 grams (13.4 ounces)	Display Unit: approx. 380 grams (13.4 ounces)	
Cleaning	Cleaned and disinfected by rubbing or immersion in isopropyl alcohol	Cleaned and disinfected by rubbing or immersion in isopropyl alcohol	Same

### Comparison- Data Transfer & Storage

The following table provides a comparison of data transfer and storage characteristics between the New Wave System and the Flexset System:

Feature/Function	New Wave	Flexset System (K233403)	Comments
Internal Data Storage	Up to 25 hours of EEG recordings	Up to 250 hours of EEG recordings	Subject device stores 10 EEG recordings up to 2.5 hours and the predicate device stores 10 EEG recordings of longer duration, which is appropriate based on the updated intended use application.
Wireless Data Transfer	Wi-Fi 802.11 a/b/g/n/ac 5G Hz LTE	Wi-Fi 802.11 a/b/g/n/ac 4G Hz LTE	The subject device supports 5G Hz LTE wireless data transfer, representing an upgrade from the predicate's 4G Hz LTE capability. This enhancement improves data transfer speed and reliability while maintaining the same fundamental wireless communication technology. The upgrade does not change the device's core functionality or raise new questions of safety or effectiveness.



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Feature/Function	New Wave	Flexset System (K233403)	Comments
Maximum Wireless Transfer Distance	Display unit includes commercially available, FCC-certified, Wi-Fi device that works for standard transfer distance from WiFi Router, typically up to 30 meters.	Display unit includes commercially available, FCC-certified, Wi-Fi device that works for standard transfer distance from WiFi Router, typically up to 30 meters.	Same

### Comparison- EEG Measurements

The following table provides a comparison of EEG measurement characteristics between the New Wave System and the Flexset System:

Feature/Function	New Wave	Flexset System (K233403)	Comments
Definition	19 EEG electrodes + Up to 8 auxiliary electrode lead wire ports (2 on the sides of the Head Unit and 6 on the Extension Unit)	19 EEG electrodes + Up to 8 auxiliary electrode lead wire ports (2 on the sides of the Flexset Unit and 6 on the Extension Unit)	Same
Signal Processing Techniques	Sampling Rate: 500 s/s  No hardware LPF/HPF/Notch filters. Software Filtering: Following are optional: LPF and HPF (Cutoff frequency selectable by operator), 50Hz, 60Hz notch	Sampling Rate: 500 s/s  No hardware LPF/HPF/Notch filters. Software Filtering: Following are optional: LPF and HPF (Cutoff frequency selectable by operator), 50Hz, 60Hz notch	Same
Accuracy Performance	Sampling rate: 500 Hz Dynamic range: $\pm 375$ mV Resolution: 44.7 nV Peak-to-peak noise: 6 $\mu$ V Common-mode rejection ratio: > 90 dB Input impedance: 1 T $\Omega$	Sampling rate: 500 Hz Dynamic range: $\pm 375$ mV Resolution: 44.7 nV Peak-to-peak noise: 6 $\mu$ V Common-mode rejection ratio: > 90 dB Input impedance: 1 T $\Omega$	Same



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	Noise: 1 $\mu$ V RMS A/D Conversion: 24 Bit	Noise: 1 $\mu$ V RMS A/D Conversion: 24 Bit	
Headset Material	Semi-rigid and flexible polymer material (e.g., Polyamide PA12, polyetherimide, polypropylene, polyimide, polydimethylsiloxane)	Semi-rigid and flexible polymer material (e.g., Polyamide PA12, polyetherimide, polypropylene, polyimide, polydimethylsiloxane)	Same
Electrode Type	Active, dry	Active, dry	Same
Contact quality/ Impedance measurement	Contact quality monitoring performed real time throughout the test. Additionally, impedance measurement mode available, typically performed by operator before the start of EEG test.	Contact quality monitoring performed real time throughout the test. Additionally, impedance measurement mode available, typically performed by operator before the start of EEG test.	Same
Contact Quality Indicators	LED indicators (tuned on optionally) for contact quality of each electrode on the headset. Same as shown on the client application of predicate	LED indicators (tuned on optionally) for contact quality of each electrode on the headset.	Same

### Comparison- Orientation Sensor

Feature/Function	New Wave	Flexset System (K233403)	Comments
Scope of Use	Used primarily as an aid for motion detection and hence finding EEG artifacts	Used primarily as an aid for motion detection and hence finding EEG artifacts	Same
Channels	Dynamic Range: -180° to 180° Three channels (X, Y, Z) used by software to measure movement and position	Dynamic Range: -180° to 180° Three channels (X, Y, Z) used by software to measure movement and position	Same



**Comparison- Software Characteristics**

Feature/Function	New Wave	Flexset System (K233403)	Comments
Firmware	Head unit is controlled by firmware.	Flexset headset is controlled by firmware.	Same
Data Center Application	Display Unit sends data to the data center application (same as K233403) in the cloud.	Flexset Display Unit sends data to the data center application in the cloud.	Same
Client Application	Client application (same as K233403) presents waveforms, controls EEG session, and offers standard EEG transformations such as low-pass, high-pass and notch filters and montage transformations.  Client application (same as K233403) records and retrieves EEG waveforms.	Client application presents waveforms, controls EEG session, and offers standard EEG transformations such as low-pass, high-pass and notch filters and montage transformations.  Client application records and retrieves EEG waveforms.	Same

**Comparison- Technological Comparison**

Feature/Function	New Wave	Flexset System (K233403)	Comments
Electrode Material	Ag/AgCl coated with optional gel tip	Ag/AgCl coated with optional gel tip	Same
Type of Electrodes	Active, dry	Active, dry	Same
Electrode Shapes	Flat and bristle type electrodes	Flat and bristle type electrodes	Same
Fitting to the Head	Flexible, wearable headset that can be stretched and put on the head.	Flexible, wearable headset that can be stretched and put on the head.	Same
Electrode Mounting Mechanism	Electrode positions are fixed and stretch based on head size. Flexible electrode legs.	Electrode positions are fixed and stretch based on head size. Flexible electrode legs.	Same



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Feature/Function	New Wave	Flexset System (K233403)	Comments
Typical Usage Setting	Intended for use for home and healthcare settings per the 10-20 EEG system	Intended for use for healthcare, home and transport settings per the 10-20 EEG system	The New Wave is limited to home and healthcare settings (outpatient healthcare facilities), while the predicate device is intended for broader use environments. This narrower intended use environment falls within the scope of the predicate and does not raise new questions of safety or effectiveness.

## Performance Data

### Software Verification and Validation Testing

No software verification and validation testing was conducted because the New Wave uses the same software as the predicate device, Flexset System (K233403). The firmware and client application remain materially unchanged between the two devices.


As the software is the same as the software on the predicate device, additional software verification and validation testing is not necessary.

### Clinical Performance Testing

No clinical performance testing was required because the New Wave maintains the same technological characteristics, signal acquisition performance, and clinical functionality as the predicate device. The only differences are a narrower use environment and a reduced maximum recording duration, neither of which affect the device's ability to acquire EEG or auxiliary signals. As the device operates within the same validated performance parameters as the predicate and no changes impact clinical performance, clinical testing is not warranted.

### Conclusion

The New Wave is substantially equivalent to the predicate device, Flexset System (K233403). The devices share near identical technological characteristics, intended use, and functionality with the predicate device.

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The New Wave differs only in having a narrower intended use environment (home and outpatient healthcare facilities only) and reduced operating time (2.5 hours versus 6-7 hours). These differences represent a subset of the predicate's approved scope and do not raise new questions of safety or effectiveness.