April 17, 2018

Zeto, Inc.
% Donna-Bea Tillman, PhD
Team Leader and Senior Consultant, Medical Devices
Biologics Consulting Group
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K172735
Trade/Device Name: WR19 System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: March 16, 2018
Received: March 19, 2018

Dear Dr. Tillman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172735

Device Name
WR19 System

Indications for Use *(Describe)*
The WR19 System is intended for prescription use in a health care facility or clinical research environment to acquire, transmit, display and store primarily EEG and optional auxiliary signals for adults and children, not including newborns.

The WR19 System requires operation by a healthcare professional familiar with EEG.

The WR19 System acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), accelerometer, photic sensor, external trigger signals and video.

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

K172735

Submitter Name	Zeto, Inc.
Submitter Address	2336 Park Ave Santa Clara, CA 95050
Submitter Tel. Number	(408) 658-0737
Contact Person	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting Group dtillman@biologicsconsulting.com Phone: (410) 531-6542 Fax: (703) 548-745
Date Prepared	April 16th, 2018
Trade Name	WR19 System
Common Name	Full-montage standard electroencephalograph
Classification Name	Electroencephalograph 21 CFR 882.1400
Product Codes	GWQ, GXY
Primary Predicate	K131383 X10 Headset with X-series Basic Software, X24 Headset with X-series Basic Software
Reference Predicate	K171669 g.Nautilus PRO

1. DEVICE DESCRIPTION

The WR19 System is primarily intended to acquire, transmit, display and store EEG and optionally do so for auxiliary signals. WR19 headset is designed to perform Routine or Outpatient EEG using 19 dry signal electrodes and 1 dedicated dry ground/driven-right-leg (DRL) electrode, adjusted and placed to comply with the 10-20 EEG system.

The device consists of the following components:

- Headset
- Electrodes (affixed to the underside of the headset)
- Charger
- Charging cable
- Software
    - Headset firmware
    - Client application
    - Data center application

2. INTENDED USE

The WR19 System is intended for prescription use in a health care facility or clinical research environment to acquire, transmit, display and store primarily EEG and optionally auxiliary signals for adults and children, not including newborns.

The WR19 System requires operation by a healthcare professional familiar with EEG.

The WR19 System acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), accelerometer, photic sensor, external trigger signals and video.

3. SUBSTANTIAL EQUIVALENCE DISCUSSION

The primary predicate device is the X-Series System (models X10 and X24) (cleared in K131383). The reference device for dry electrodes is the g.Nautilus PRO (cleared in K171669).

3.1. Technological Comparison to Predicate Device

The following tables provide comparisons of technological characteristics between the WR19 System and the X-Series System.

3.1.1. Comparison - Overview

The following tables provide a comparison of the technological characteristics between the WR19 System and the X-Series System:

	Subject Device **WR19 System K172735**	**Predicate Device X-Series System K131383**	**Remarks**
User Interface	Operator control, visual indicators	Operator control, visual indicators	**Same**
System Components	• Headset • Electrodes • Charger • Charging cable • Software	• Headset (Electronics box) • Electrode strip • Electrodes • Neoprene Strap • Charger • Charging cable • Software	**No significant difference.** Since WR19 works via the cloud, it uses a data center application, as opposed to just using client software

	Subject Device **WR19 System** **K172735**	**Predicate Device X-Series System** **K131383**	**Remarks**
Signals Acquired	• Scalp EEG • Accelerometer • Optional non-EEG signals:	• Scalp EEG • 3-D actigraphy (accelerometer based) • Optional non-EEG signals:	**Same** in measuring EEG signals, but the subject device offers a different subset of optional auxiliary features.
Power Supply	1 x 2050mAh 3.7V Lithium Ion battery	2 to 4 x 240mAh 3.7 Li- Ion batteries	**No significant difference.** WR19 uses a bigger battery because a higher sampling rate generates more data and requires more power.
Battery Charging	Via USB connector connected to USB wall charger.	Via JED Connector connected to USB port or USB wall charger	**Same**
Typical Charging Time	0.5-6.0 hours	0.5-5.0 hours	**Same**
Operating Time	6-7 hours	Monitoring Days after Charge/Hours of Use • 0-4 Days: 16 to 17 hours • 5-10 Days: 14 to 15 hours	**No significant difference**
Typical use duration	20 - 60 minutes	Not specified	**Comparison not available;** however, the typical use duration of the subject device is standard for outpatient / routine EEG recording

	Subject Device **WR19 System** **K172735**	**Predicate Device X-Series System** **K131383**	**Remarks**
Dimensions	8.5 x 10.8 x 5.7" or 214 x 274 x 144 mm (Complete headset with electrodes)	5.0" long, 2.25" wide, 1.0" deep (Electronics box)	**No significant difference.** WR19 System contains a headset worn like a bike helmet. The electronics are integrated into the headset. Predicate has flexible electrode strips that attach to Velcro bands that hold an electronics housing. Hence dimensions vary.
Weight	< 650g or 23oz with battery (Complete headset with electrodes)	3.9oz with two batteries (Electronics box)	**No significant difference.** Refer to row above for comparison of dimensions.
Cleaning	Cleaned and disinfected by rubbing with isopropyl alcohol	Cleaned and disinfected by rubbing with isopropyl alcohol	**No significant difference.** Unlike predicate, WR19 uses dry electrodes that do not require gel/paste to operate. Hence, a gel/paste residue is not left behind.

3.1.2. Comparison – Data Transfer and Storage

The following tables provide a comparison of data transfer and storage characteristics between the WR19 System and the X-Series System:

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Internal data Storage	SD card, Minimum 8GB memory capacity	Not used. The X-Series system does not include a recording mode where data is stored on the recorder.	**No significant difference**. WR19 has built-in memory buffer capacity to smooth temporary slowing of data communication, but WR19 also offers a backup solution during total loss of communication.
File Size per 8 hr. recording	1.5 GB	512 MB	**No significant difference**. WR19 uses higher sampling rate and hence file size is higher.
Wireless Data Transfer	802.11 b/g/n Wi-Fi	Bluetooth 2.0	**No significant difference**. The nature of the data transmission protocol yields a higher data throughput and more reliable connection.
Maximum wireless transfer distance	Headset includes commercially available, FCC-certified, Wi-Fi module that works for standard transfer distance from Wi-Fi Router, typically up to 30 meters.	Transfer distance 10 m line of sight, maximum transfer rate 3 Mbaud	**No significant difference**. WR19 offers a longer data transfer range.

3.1.3. Comparison – EEG Measurements

The following table provides a comparison of EEG measurement characteristics between the WR19 System and the X-Series System:

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Definition	Up to 19 referential channels	Up to 20 differential or referential channels	**Same as predicate.** WR19 does not offer differential variations in hardware but can be changed with software montages, typical of Full Montage EEG systems.
Signal Processing Techniques	Sampling Rate: 500 s/s	Sampling Rate: 256 s/s	**No significant difference**. WR19 provides higher temporal signal resolution.
	No hardware LPF/HPF/Notch filters.	Hardware filters: 0.1Hz HPF, 100Hz LPF	**No significant difference**. WR19 does not limit the operator/EEG reviewer as it does not use any hardwired filters.
	Software Filtering: Following are optional: LPF and HPF (Cutoff frequency selectable by operator), 50Hz, 60Hz notch	Software Filtering: 50, 60 Hz notch	**Same as predicate.** WR19 also offers a wider range of operator selectable filters.

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Accuracy, Performance	Sampling rate: 500 Hz Dynamic range: +/- 375 mV Resolution: 0.044 µV Peak to peak noise: 4 µV (typical) Common Mode Rejection Ratio: > 120dB (typical) Input Impedance: 1000 GOhm Noise: 1µV RMS A/D Conversion: 24 Bit	Sampling rate: 256 Hz Dynamic range: +/- 1000µV Resolution: 0.03µV Peak to peak noise: 3.7 µV (typical) Common Mode Rejection Ratio: 110dB (typical) Input Impedance: 100 GOhm Noise: RMS not specified	**No significant difference**
Headset material	Semi-rigid and flexible polymer material (e.g., Polyamide PA12, ABS, Polyurethane and Polycarbonate)	Neoprene strap, flexible plastic type strips that hold foam electrodes filled with gel, rear electronics casing (material not specified)	**No significant difference.** Both devices passed applicable Biocompatibility tests outlined in relevant standards.
Electrode type	Active, dry	Passive, wet	**No significant difference**
Contact quality/Impedance measurement	Contact quality monitoring performed real time throughout the recording/ test	Impedance measurement performed by operator before the start of EEG test during 'Test Impedance' mode.	**No significant difference**

3.1.4. Comparison – ECG Measurements

The following table provides a comparison of ECG measurement characteristics between the WR19 System and the X-Series System.

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Channels	Single Differential ECG using non-active (passive), electrodes (optional) (ECG lead wire and electrodes not included)	Single Differential ECG (optional) (ECG cable included)	**No significant difference**
Accuracy, performance	Sampling rate: 500 Hz Dynamic range: +/- 3900 mV Resolution: 0.536 µV Peak to peak noise: 4 µV Common Mode Rejection Ratio: > 110dB (typical) Input Impedance: 500 MOhm A/D Conversion: 24 Bit Noise: 1 µV RMS	Sampling rate: 256 Hz Dynamic range: +/- 2000 µV Resolution: 0.06 µV Peak to peak noise: 4.2 µV Common Mode Rejection Ratio: > 110dB (typical) Input Impedance: 100 GOhm A/D Conversion: 16 Bit Noise: not specified	**No significant differences.** The amplitudes of heartbeat electrical signals are of the order of millivolts.

3.1.5. Comparison – Accelerometer

The following table provides a comparison of accelerometer characteristics between the WR19 System and the X-Series System.

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Scope of use	Used primarily as an aid for motion detection and hence finding EEG artifacts	Used primarily as part of a 3-D actigraphy for monitoring rest/ non-specific activity cycles	**No significant difference.** WR19 intended scope is a subset of the predicate.

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 as predicate device**

3.1.6. Comparison – Software Characteristics

The following table provides a comparison of software technological characteristics between the WR19 System and the X-Series System:

	Subject Device **WR19 System** **K172735**	**Predicate Device** **X-Series System** **K131383**	**Remarks**
Firmware	WR19 headset is controlled by a firmware.	X-series headset is controlled by a firmware (No more details specified)	**Same as predicate device**
Data center application	WR19 sends data to the data center application in the cloud.	Not applicable.	**No significant difference.** Predicate is not a cloud solution.
Client application	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 presents waveforms (No more details specified)	**No significant difference**
	Client application records and retrieves EEG waveforms.	Client application presents waveforms (No more details specified)	**No significant difference.** Predicate uses 3rd party software to retrieve and display waveforms.

3.2. Technological Comparison to Reference Device

The following table provides a comparison of electrode technological characteristics between the WR19 System and the g.Nautilus PRO:

	Subject Device **WR19 System** **K172735**	**Reference Device** **g.Nautilus PRO** **K171669**	**Remarks**
Electrode material	Ag/AgCl coated	Gold or Ag/AgCl coated	**Same as reference predicate**
Type of electrodes	Active, dry	Active, wet or dry	**Same as reference predicate**
Electrode mounting mechanism	Semi-rigid wearable headset with certain electrode positions. Electrode positions can be adjusted to a limited extent	Elastic EEG cap with chin strap with certain electrode positions	**No significant difference**
Typical usage setting	Intended for use for Routine clinical EEG where rapid placement of EEG electrodes as per the 10-20 EEG system is required	Intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired	**Same as reference predicate**

4. PERFORMANCE DATA

The following performance testing was provided to support the substantial equivalence of the subject device:

- EEG performance testing, as per IEC 60601-2-26:2012
- Testing of dry electrode input buffers (modified IEC 60601-2-26 testing)
- Testing to verify functionality of optional auxiliary signals:
  - Infrared receiver
  - Infrared transmitter
  - External optical input
  - Photic trigger detector
  - ECG input
  - Accelerometer
  - Video capture
  - Contact quality detection feature

5. STANDARDS

The table below provides the complete list of standards that are used in the 510(k) to establish device performance and support substantial equivalence:

Standard	Title
ANSI / AAMI 60601-1:2005 + A1:2012	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-6:2010 + A1:2013	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 60601-1-2:2014	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	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
ISO 14971:2007	Medical Devices - Application of Risk Management to Medical Devices
ANSI/AAMI 62304:2006 + A1:2015	Medical Device Software - Software Life Cycle Processes
ISO 10993-1:2009 + TC:2010	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
ANSI / AAMI 62366:2007 + A1:2014	Consolidated Version Medical Devices - Application Of Usability Engineering To Medical Devices

6. STERILIZATION, SHELF LIFE, CLEANING, REUSE

The WR19 System is neither shipped nor intended to be used sterile. The device is reusable, is intended for multi-patient use, and is intended to be cleaned and disinfected between uses.

7. BIOCOMPATIBILITY

The patient-contacting materials of the WR19 System are all either limited duration (<24 h) skin or hair-contacting. Accordingly, cytotoxicity, maximization sensitization, and skin irritation testing were done as per **ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010**. The results of all tests showed no evidence of toxic potential or adverse reactions.

8. CLINICAL PERFORMANCE TESTING

Clinical testing was performed at a United States hospital to demonstrate that the WR19 System's electrode variations provide EEG signal quality that is comparable to a common EEG device cleared in K163163 - XLTEK EMU40EX. 7 subjects in 2 study cohorts (EEG patients and healthy volunteers) for 15-30 minutes of recording (2 cohorts, of EEG patients and healthy volunteers, 2 subjects each) and 2 hours (1 sub-cohort of healthy volunteers, 3 subjects). Healthy volunteers in both recording durations were asked to generate sources of artifact and/ or error. The results of time to setup, qualitative waveform comparisons, Likert scoring, and spectral correlation and SNR comparisons were analyzed to assess device performance. The subject device was found to perform at least as well as the comparator device based on predefined acceptance criteria.

9. SOFTWARE DOCUMENTATION

Software documentation up to a **Moderate** Level of Concern device is provided in support of the WR19 System.

10. ELECTRICAL SAFETY

The WR19 System was evaluated and the device was found to conform to ANSI / AAMI 60601-1:2005 + A1:2012.

11. ELECTROMAGNETIC COMPATIBILITY

The WR19 System was evaluated and found to conform to IEC 60601-1-2:2014. In addition, wireless coexistence testing was conducted, per FDA's Guidance Document entitled "Radio Frequency Wireless Technology in Medical Devices issued on August 14, 2013.

12. SUBSTANTIAL EQUIVALENCE CONCLUSION

Based on the comparison of intended use, technological characteristics to the previously cleared X-Series System (models X10 and X24) (K131383) as well as performance testing, and conformance with applicable standards, differences do not raise new questions of safety and effectiveness and the WR19 System is substantially equivalent to the predicate device.