April 30, 2024

Zeto, Inc.
% Mary Vater
Consulting Partner
Medical Device Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K233403
Trade/Device Name: Flexset System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: March 22, 2024
Received: March 29, 2024

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 (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.

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,

FDA Patrick Antkowiak -S

for
Jay Gupta, MS
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)*

K233403

Device Name

Flexset System

Indications for Use *(Describe)*

The Flexset system is intended for prescription use in a healthcare facility, home, and specific transport environments to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The Flexset 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Flexset System

Device Common Name: Full-montage standard electroencephalograph

Device Trade Name: Flexset System

Applicant: Zeto, Inc.
4917 Waters Edge Dr. Suite #221
Raleigh, NC, 27606

Contact: Aswin Gunasekar
CEO, Zeto, Inc.
(833) 938-6334

Classification Name: Electroencephalograph

Classification Regulation: 21 CFR 882.1400, Class II

Panel: Neurology

Primary Product Code: GWQ

Secondary Product Code: GXY

Predicate Devices: Zeto WR19 System (K172735, primary), X-Series System (K131383, secondary)

Submission number: K233403

Date: 2024-04-29

1. Indications for use

The Flexset system is intended for prescription use in a healthcare facility, home, and specific transport environments to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The Flexset 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.

2. Device Description

The Flexset System is intended to acquire, transmit, display and store primarily EEG and optionally auxiliary signals. Specific transport environments in the Indications for Use include ambulances, cars, buses, trains, boats and via air, per stipulation in the user manual of the device. The Flexset headset is designed to record a full montage EEG, with optional external references and additionally up to 8 auxiliary channels using lead wires for EEG, EOG, ECG or EMG. The device consists of the following components:

- Flexset (Headset)
- Electrodes
- Charger with cable
- Display Unit
- Extension Unit
- Lead wires
- Software
    - Display Unit firmware
    - Data center application (same as K172735)
    - Client application (same as K172735)

3. SUBSTANTIAL EQUIVALENCE DISCUSSION

3.1. Predicate Devices

The cited predicate device is the WR19 System, manufactured by Zeto, Inc., and cleared under K172735. The secondary predicate device, X-Series System by Advanced Brain Monitoring, Inc., cleared under K131383 is cited for the following features:

- EOG
- EMG
- Home environment

3.2. Indications for Use Comparison

3.2.1. Indications for Use, Predicate Device (WR19 System)

"The WR19 System is intended for prescription use in the 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 Flexset System requires operation by a healthcare professional familiar with EEG. The Flexset System acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), accelerometer, photic trigger detection, external trigger signals and video."

3.2.2. Indications for Use, Secondary Predicate Device (ABM X-Series System, K131383)

"The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals.
The X-Series 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."

3.2.3. Indications for Use, Flexset System

"The Flexset system is intended for prescription use in a healthcare facility, home, and specific transport environments to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The Flexset 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."

3.2.4. Similarities

- Both devices are intended for prescription use.
- Both devices are intended for use in a healthcare facility or clinical research environment.
- Both devices cover adults and children, not including newborns.
- Both devices acquire, transmit, display, and store their respective signals.
- Both devices operate on electroencephalogram (EEG), electrocardiogram (ECG), accelerometer (same as orientation sensor), photic trigger detection, external trigger signals and video.

3.2.5. Differences

- The WR19 System in addition to 'prescription use' is indicated for use by 'a healthcare professional familiar with EEG'. Since the latter phrase is redundant with 'prescription use', the Flexset system specifies only 'prescription use' to remove inconsistencies and hence raises no new concerns.
- The Flexset System is indicated for use in the home and air transport environments as well, whereas the WR19 System is not; the secondary predicate (X-Series System, K131383 which was the predicate of our WR19, K172735 submission) has been added for home use. Listed transport environments have also been covered. Additionally, compatibility with elevated EMC environments in air transport use has been validated for compliance with RTCA DO-160F. This raises no new concerns because compliance to safety and efficacy standards for the additional environments have been validated in this submission.
- The Flexset System is indicated to operate on optional EOG and EMG signals, whereas the WR19 System is not; the X-Series System contains EOG and EMG and comparison details have been added to the substantial equivalence table.

This raises no new concerns as these two signals use the same essential physiological measurement circuitry as EEG and ECG.

3.2.6. Conclusion of the comparison of the indications for use

The differences in indications for use between the subject device and the predicate devices, indicate that the intended use of the devices are the same; the differences do not raise any concerns of safety and effectiveness not raised for the predicate devices, nor do the indications have the potential to significantly increase a safety or effectiveness concern raised for the predicate devices.

3.3. Substantial equivalence comparison tables

3.3.1. Comparison – Overview

The following table provides a comparison of overview of the technological characteristics between the Flexset System and the WR19 System:

Comparison - overview	**Flexset System (This submission)**	**WR19 System (Predicate device K172735)**	**Remarks**
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	**Same**
Regulation Name	Electroencephalograph	Electroencephalograph	**Same**
Regulatory Class	II	II	**Same**
Product Code	GWQ	GWQ	**Same**
Subsequent Product Code	GXY	GXY	**Same**
Manufacturer	Zeto, Inc.	Zeto, Inc.	**Same**
User Interface	Operator control, visual indicators	Operator control, visual indicators	**Same**
System Components	● Flexset (Headset) ● Electrodes ● Charger with cable ● Display Unit ● Extension Unit ● Lead wires ● Software ○ Firmware and Display Unit Software ○ Data center application (same as K172735) ○ Client application (same as K172735)	● Headset ● Electrodes ● Charger ● Charging cable ● Software ○ Headset firmware ○ Data center application ○ Client application	**No significant difference. Substantially equivalent. The Display Unit provides easier control and additional display capability.**

Signals Acquired	● Scalp EEG ● Orientation Sensor (accelerometer) ● Optional non-EEG signals: ○ ECG ○ EOG ○ EMG ○ Photic trigger detection ○ External trigger input ○ Video	● Scalp EEG ● Accelerometer ● Optional non-EEG signals: ○ ECG ○ Photic trigger detection ○ External trigger input ○ Video	**Same in measuring EEG, but offers additional, optional auxiliary signal measurements.**
Power Supply	1 × 3950mAh 3.85V Lithium-Ion battery	1 x 2050mAh 3.7V Lithium-Ion battery	**No significant difference. Flexset system uses a higher capacity battery.**
Battery Charging	Medical grade wall charger	Via USB connector connected to USB wall charger.	**No significant difference. Both accomplish safe and quick charging**
Typical Charging Time	0.5-6.0 hours	0.5-6.0 hours	**Same**
Operating Time	6-7 hours	6-7 hours	**Same**
Typical use duration	20 mins to several hours	20 - 60 minutes	**No significant difference. Flexset system can be used for longer relative to predicate as it weighs less and is more comfortable.**
Dimensions	7.25 x 7.25 x 5.25" or 184 x 184 x 133 mm	8.5 x 10.8 x 5.7" or 214 x 274 x 144 mm	**No significant difference**
Weight	Approx 400 g or 14 oz	< 650g or 23 oz with battery	**No significant difference. Lighter, Substantially equivalent**
Cleaning	Cleaned and disinfected by rubbing or immersion in isopropyl alcohol	Cleaned and disinfected by rubbing with isopropyl alcohol	**No significant difference. Flexset can be immersion cleaned as well.**

3.3.2. Comparison - Data Transfer & Storage

The following table provides a comparison of data transfer and storage characteristics between the Flexset System and the WR19 System:

Comparison - Data Transfer & Storage	Flexset System (This submission)	WR19 System (Predicate device K172735)	Remarks
Internal data Storage	Built-in device memory, 64 GB	SD card, Minimum 8GB	**No significant difference. Substantially equivalent.**
File Size per 8 hr recording	1.5 GB	1.5 GB	**Same**
Wireless Data Transfer	Wi-Fi 802.11 a/b/g/n/ac 2.4 GHz or 5 GHz LTE	Wi-Fi 802.11 b/g/n	**No significant difference. Flexset system provides more options.**
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.	Headset includes commercially available, FCC-certified, Wi-Fi module that works for standard transfer distance from WiFi Router, typically up to 30 meters.	**Same**

3.3.3. Comparison - EEG Measurements

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

Comparison - EEG Measurements	Flexset System (This submission)	WR19 System (Predicate device K172735)	Remarks
Definition	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)	19 EEG	**Same in measuring EEG. The subject device offers additional optional auxiliary signals for measurement. Auxiliary EMG and EOG channels covered by secondary predicate below.**
Signal Processing Techniques	Sampling Rate: 500 s/s	Sampling Rate: 500 s/s	**Same**
	No hardware LPF/HPF/Notch filters. Software Filtering: Following are optional: LPF and HPF (Cutoff frequency selectable by operator), 50Hz, 60Hz notch	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: ± 375 mV Resolution: 44.7 nV Peak-to-peak noise: 4 µV Common-mode rejection ratio: > 120 dB Input impedance: 1 TΩ Noise: 1 µV RMS A/D Conversion: 24 Bit	Sampling rate: 500 Hz Dynamic range: +/- 375 mV Resolution: 44.7 nV Peak to peak noise: 4 µV Common Mode Rejection Ratio: > 120dB Input Impedance: 1 TΩ Noise: 1 µV RMS A/D Conversion: 24 Bit	**No significant difference. Both satisfy clinical EEG requirements**
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, ABS, Polyurethane and Polycarbonate)	**No significant difference. Both use safe, biocompatibility tested plastic materials**
Electrode type	Active, dry	Active, dry	**Same**
Contact quality/Impedance measurement	Contact quality monitoring performed real time throughout the test. Additionally, impedance measurement mode is available, typically performed by the operator before the start of EEG study.	Contact quality monitoring performed real time throughout the test	**No significant difference.** **Flexset system offers additional impedance monitoring**
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	None on the headset itself	**No significant difference.** **Flexset offers additional status display, redundant to onscreen display**

3.3.4. Comparison - ECG Measurements

The following table provides a comparison of ECG measurement characteristics between the Flexset System and the WR19 System:

Comparison - ECG Measurements	**Flexset System (This submission)**	**WR19 System (Predicate device K172735)**	**Remarks**
Channels	Single Differential ECG using non-active (passive), gel-based leads/electrodes (optional)	Single Differential ECG using non-active (passive), gel-based leads/electrodes (optional)	**Same**
Accuracy, performance	Sampling rate: 500 Hz Dynamic range: +/- 3900 mV Resolution: 0.536 µV Peak to peak noise: 4 µV Common Mode Rejection Ratio: > 110 dB Input Impedance: >1 TΩ A/D Conversion: 24 Bit	Sampling rate: 500 Hz Dynamic range: +/- 3900 mV Resolution: 0.536 µV Peak to peak noise: 4 µV Common Mode Rejection Ratio: > 110dB Input Impedance: 500 MOhm A/D Conversion: 24 Bit	**No significant difference.**

3.3.5. Comparison – Accelerometer

The following table provides a comparison of accelerometer characteristics between the Flexset System and the WR19 System:

Comparison - Accelerometer	Flexset System (This submission)	WR19 System (Predicate device K172735)	Remarks
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**

3.3.6. Comparison - Software Characteristics

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

Comparison - Software Characteristics	Flexset System (This submission)	WR19 System (Predicate device K172735)	Remarks
Firmware	Flexset headset is controlled by firmware.	WR19 headset is controlled by firmware.	**Same**
Data center application	Flexset Display Unit sends data to the data center application (same as K172735) in the cloud.	WR19 headset sends data to the data center application in the cloud.	**Same**
Client application	Client application (same as K172735) 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, controls EEG session, and offers standard EEG transformations such as low-pass, high-pass and notch filters and montage transformations.	**Same**
	Client application (same as K172735) records and retrieves EEG waveforms.	Client application records and retrieves EEG waveforms.	**Same**

3.3.7. Electrode technological comparison

The following table provides a comparison of electrode technological characteristics between the Flexset System and the WR19 System:

Technological Comparison	Flexset System (This submission)	WR19 System (Predicate device K172735)	Remarks
Electrode material	Ag/AgCl coated with optional gel tip	Ag/AgCl coated	**No significant difference. Optional gel tip increases comfort.**
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.	Semi-rigid wearable headset with each band adjusted via dials.	**No significant difference. Both**

			conform to the head.
Electrode mounting mechanism	Electrode positions are fixed and stretch based on head size. Flexible electrode legs.	Electrode positions can be adjusted to a limited extent. Spring-loaded mechanism in the electrode holder.	**No significant difference. Both make stable electrode contact with the scalp.**
Typical usage setting	Intended for use for healthcare, research, home, ground and air transport settings per the 10-20 EEG system	Intended for use for Routine clinical EEG where rapid placement of EEG electrodes as per the 10-20 EEG system is required	**No significant difference. Flexset system offers additional use settings.**

3.3.8. Comparison - Secondary Predicate Device

The following table provides a comparison of the Flexset System and the X-Series System, with s focus on non-ECG auxiliary signals and use environment:

Specification	**Flexset System (This submission)**	**X-Series System secondary predicate device, K131383)**	**Remarks**
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	**Same**
Regulation Name	Electroencephalograph	Electroencephalograph	**Same**
Regulatory Class	II	II	**Same**
Product Code	GWQ	GWQ	**Same**
Manufacturer	Zeto, Inc.	Advanced Brain Monitoring, Inc.	**Different**
Signals Acquired	● Scalp EEG ● Orientation Sensor (accelerometer) ● Optional non-EEG signals: ○ ECG ○ EOG ○ EMG ○ Photic trigger detection ○ External trigger input ○ Video	● Scalp EEG ● 3-D actigraphy ● Optional non-EEG signals: ○ ECG ○ EOG ○ EMG	**No significant difference. Other non-EEG signals covered against predicate.**
Non-ECG auxiliary measurements definition	Up to 8 auxiliary lead wire ports (2 on the sides of the Flexset Unit and 6 on the Extension Unit) Provided as accessories: Lead wires for HEOG+, HEOG-, VEOG+, VEOG-, EMG1+ and	Up to 4 optional single channels either dual lead electrooculogram (EoG) or electromyogram (EMG)	**More available channels in the submitted device. Same**

	EMG1-		
Signal processing techniques for non-ECG auxiliary measurements	Software: high-pass, low-pass, notch with configurable frequencies.	0.1 Hz High Pass, hardware 100 Hz Low Pass, hardware	**Same as predicate device, additional configurability in submitted device**
Accuracy of non-ECG auxiliary measurements	Sampling rate (for all types): 500 Hz Dynamic range (for all types): ± 375 mV Resolution (for all types): 44.7 nV Peak-to-peak noise: 4 µV	Sampling rate in both cases 256 Hz EOG: Dynamic Range: +/- 2 mV Resolution: 60 nV Peak-to-peak noise: 4.2 µV EMG: Dynamic Range: +/- 1 mV Resolution: 30 nV Peak-to-peak noise: 3.7 µV	**Same, higher sampling rate in the submitted device.**
Typical usage setting	Intended for use for healthcare, research, home and transport settings per the 10-20 EEG system	Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting) Clinical Research Environment	**No significant difference except for addition of air transport for subject device. Supporting information provided.**

4. STERILIZATION, SHELF LIFE, CLEANING, REUSE

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

5. Biocompatibility

The patient-contacting materials of the Flexset System are all either limited duration (<24 h) skin or hair-contacting. Accordingly, cytotoxicity, maximization sensitization, and skin irritation testing were done as per the following standards:

- ISO 10993-1:2018
- ISO 10993-5: 2009(E)
- ISO 10993-10: 2021(E)
- ISO 10993-23:2021(E)

The results of all tests showed no evidence of toxic potential or adverse reactions.

6. PERFORMANCE DATA

The following standards' performance tests were conducted to support the performance claims of the product:

- EEG performance testing, as per IEC 80601-2-26:2019
- IEC 60601-1-2:2014+AMD1:2020
- Testing to verify functionality of optional auxiliary signals
- IEC TR 60601-4-2:2016

7. SOFTWARE DOCUMENTATION

The documentation level evaluation concluded that the device requires basic documentation.

8. ELECTRICAL SAFETY TESTING

The Flexset System was evaluated as per IEC 60601-1:2005+AMD1:2012+AMD2:2020 , and found to be compliant.

9. ELECTROMAGNETIC COMPATIBILITY TESTING

The Flexset System was evaluated as per IEC 60601-1-2:2014+AMD1:2020, and found to be compliant. In addition, wireless coexistence testing was conducted.

10. STANDARDS

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

Standard	**Title**
IEC 60601-1:2005+AMD1:2012+AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+AMD1:2020	Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 80601-2-26:2019	Medical electrical equipment — Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2009(E)	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2021(E)	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-23:2021(E)	Biological evaluation of medical devices — Part 23: Tests for irritation
IEC 62304:2006 + A1:2015	Medical device software — Software life cycle processes — Amendment 1
IEC 60601-1-11:2015+AMD1:2020	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 — Amendment 1
IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC TR 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

11. Substantial Equivalence Conclusion

Based on the detailed comparison of specifications to the previously cleared WR19 System (K172735) and the previously cleared X-Series System (K131383), functional and performance testing, and conformance with applicable standards as well as the comparison of indications; the differences do not raise new concerns of safety and effectiveness and the Flexset System can be found substantially equivalent to the predicate devices.