February 4, 2024

X-Trodes
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group
100 Daingerfield Rd, Suite 400
Alexandria, VA 22314

Re: K232210
Trade/Device Name: X-trodes System M
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GXY, DPS, IKN
Dated: January 4, 2024
Received: January 4, 2024

Dear Donna-Bea 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 (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
Assistant Director

DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232210/S001

Device Name
X-trodes System M

Indications for Use *(Describe)*
The X-trodes System M is intended for prescription use only in the home or healthcare facility to acquire, record, transmit and display physiological signals from adult patients. The X-trodes System M acquires, records, transmits, and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer and gyroscope signals. The X-trodes System M 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.

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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1. SUBMITTER INFORMATION

Applicant:	X-trodes
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2. CORRESPONDENT INFORMATION

Contact:	Donna-Bea Tillman, Ph.D.
Title:	Senior Consultant
Firm:	Biologics Consulting Group

3. DATE PREPARED: FEBRUARY 2, 2024

4. DEVICE INFORMATION

Device Name:	X-trodes System M
Common Name:	Reduced-Montage Standard Electroencephalograph
Regulation Number:	21 CFR 882.1835

Regulation Name:	Physiological signal amplifier
Primary Product Code:	GWL
Secondary Product Codes	GXY, DPS, IKN
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Primary EEG/EOG Predicate Device Name:	Quick-20m
510(k) Number:	K203331
Manufacturer:	CGX, LLC

ECG Predicate Device Name:	Electrocardiograph (SE-1200 Pro, SE-1201 Pro)
510(k) Number:	K222902
Manufacturer:	Edan Instruments, Inc.
EMG Predicate Device Name:	Focus EMG
510(k) Number:	K102610
Manufacturer:	TeleEMG, LLC

The predicate devices have not been subject to a design related recall.

6. DEVICE DESCRIPTION

The X-trodes System M combines hardware, firmware, and software to acquire the following physiological signals: physiologic signal amplifier (EEG), electrooculography (EOG), surface electromyography (sEMG), electrocardiography (ECG), and accelerometer and gyroscope signals. It acquires physiological data through a data acquisition unit connected to electrode arrays patches, applied by a technician or patient to the patient. The data is recorded and transmitted to a cloud where it is converted to an EDF (European Data Format) format, suitable for analysis by third party software.

7. INDICATIONS FOR USE

The X-trodes System M is intended for prescription use only in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. The X-trodes System M acquires, records, transmits, and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer and gyroscope signals. The X-trodes system M 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.

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Comparison of Technological Features

	Subject Device	Primary Predicate EEG/EOG	Predicate ECG	Predicate EMG	Comments
510(k) Number	K232210	K203331	K222902	K102610	
Applicant	Xtrodes Ltd.	CGX, LLC	Edan Instruments, Inc.	TeleEMG, LLC	
Device Name	X-trodes System M	Quick-20m	Electrocardiograph (SE-1200 Pro, SE-1201 Pro)	Focus EMG	
Classification Regulation	21 CFR 882.1835 Physiological signal amplifier 21 CFR 882.1320 Cutaneous Electrode 21 CFR 870.2340 Electrocardiograph 21 CFR 890.1375 Diagnostic Electromyograph	21 CFR 882.1835 Physiological signal amplifier 21 CFR 882.1320 Cutaneous Electrode	21 CFR 870.2340 Electrocardiograph	21 CFR 890.1375 Diagnostic Electromyograph	
Product Code	GWL, GXY, DPS, IKN	GWL, GXY	DPS	IKN	
Intended Use	The X-trodes System M is intended for prescription use only in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. The X-trodes System M acquires, records, transmits, and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer and gyroscope signals. The X-trodes System M only	The Quick-20m is intended to be used to acquire electroencephalograph (EEG) and transmit it wirelessly to a computer.	The SE-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements	The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.	

	Subject Device	Primary Predicate EEG/EOG	Predicate ECG	Predicate EMG	Comments
	acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision, and reliability.		and interpretive statements is offered to clinicians on an advisory basis only.		
Patient Population	Adults	Adults	Adult and pediatric patients	Adults	Same
Environment of Use	Home, Healthcare facility,	Home or healthcare facility setting	Hospitals or healthcare facilities	Clinical environment.	The subject device and the primary predicate device are intended for use in either healthcare facility or home settings
Signals Acquired	Forehead/head EEG, EOG, EMG, ECG, Microphone, Accelerometer, Gyroscope	EEG/EOG	ECG	EMG	The subject device is a combination of the features of the predicate devices
Full scale Input Range	± 12.5 mV	± 300 mV	No information in the predicate 510(k) Summary	No information in the predicate 510(k) Summary	See Discussion item 1
A/D conversion	16 bits	24 bits	24 bits	16 Bits	Same for EMG See Discussion item 2
Sampling Frequency (Rate)	4000 Hz/Channel	500 Hz/channel	64,000 Hz	200-80000 Hz	See Discussion item 3
Frequency Response	0.35 Hz ~ 700 Hz (-3 dB)	Linear between 0.1 and 100 Hz	0.01 Hz ~ 350 Hz (-3 dB)	No information in the predicate 510(k)	XTR frequency range supersedes the predicates, thus constitutes SE.
Input Impedance	≥10 MΩ	>100 MOhm (125 Hz)	≥100 MΩ(10 Hz)	≥100 MOhm < 25pF	See Discussion item 4
DC Offset Voltage	+3000mV, -1000mV ±5%.	No information in the predicate 510(k)	±960mV, ±5%	No information in the predicate 510(k)	See Discussion item 5
Noise	<0.9 μV RMS, 1-35 Hz ≤6 μVp-p 0.5-50Hz	<0.6 μV RMS, 1-30 Hz	≤12.5 μVp-p	< 0. 6 μVrms	See Discussion item 6
Filter	Analog: 0.35-700Hz	DC up to 131 Hz	AC Filter: 50 Hz / 60 Hz / Off	Low pass filter:	Analog filter is applied prior to A/D conversion.

	Subject Device	Primary Predicate EEG/EOG	Predicate ECG	Predicate EMG	Comments
	Digital display filters: EEG: 0.32-35 Hz EOG: 0.32-35 Hz ECG: 0.32-70 Hz EMG: 10-114 Hz		DFT Filter: 0.01 Hz / 0.05 Hz / 0.32 Hz / 0.67 Hz EMG Filter: 25Hz / 35Hz / 45Hz / OFF LOWPASS Filter: 350 Hz / 300 Hz / 270 Hz / 150 Hz / 100 Hz / 75 Hz	(-12dB/octave) 10 to 10,000 High pass filter: (-6dB/octave) 0.05 to 3000 Hz	Data is delivered raw. Modality Filters are applied for Real-time display only.
Notch filter	50/60 Hz selectable	No information in the predicate 510(k)	No information in the predicate 510(k)	50/60 Hz selectable	Filters are applied for Real-time display only.
CMRR	>95 dB at 60 Hz/50Hz	>90 dB at 60 Hz	≥140 dB (AC filter on) ≥123 dB (AC filter off)	>100 dB	For EEG - Similar to predicates For ECG and EMG See Discussion item 7
Connection	Bluetooth Low Energy	Wireless to receiver, USB to computer	WIFI, 4G, Bluetooth	USB to computer	Similar to predicates
Number Of Possible Electrodes	16	20 Channels in standard 10-20 head map	10	2	Similar to predicates range. Differ for each predicate for the different electrophysiological signal application
Type of Electrodes	Dry	Dry	Body surface ECG electrodes	Stainless steel electrodes. No additional information is supplied in the predicate 510(k) summary	Similar to the EEG/EOG predicate. FDA has found dry electrodes to be substantially equivalent to gel electrodes.
Type Of Applied Part	CF	BF	CF	No information in the predicate 510(k)	Similar to predicates

9. PREDICATE DEVICE DISCUSSION ITEMS

1. Full Scale Input Range

A typical adult human **EEG** signal is about 10 µV to 100 µV in, so even if we consider 10-fold increase to this range (1mV), it is well covered within the X-trodes device's inputs range of 12.5 mV. Any input range larger than that is unnecessary.

For **ECG**, there is no information about the predicate device's input range. Therefore, we aim to establish that the X-trodes device has an input range suitable for ECG. "Normal ECG signals are time-varying signals with a small amplitude ranging from 10 µV to 5 mV" (cited from PubMed PMC7664289). The X-trodes device's input range of 12.5 mV is more than double this range.

For **EMG**, there is no information about the predicate device's input range. Therefore, we aim to establish that the X-trodes device has an input range suitable for EMG. "The amplitude range of EMG signal is 0-10 mV (+5 to -5) prior to amplification" (cited from PubMed PMC1455479). X-trodes device's input range of 12.5 mV is more than double this range.

Lastly, the results of the clinical study presented in Section 20 of the Original 510(k) submission demonstrate that the quality of the EEG/ECG/EOG/EMG waveforms is sufficient for clinical purposes. Taken together, these considerations are sufficient to demonstrate that the X-trodes device is substantially equivalent to the predicates in this aspect.

2. A/D conversion

For **EEG**, a typical adult human EEG signal is about 10 µV to 100 µV. If we consider 10fold this signal, it takes constitutes a portion of about 1000µV /300,000µV (1/300) of the predicate device's input range.

For **ECG**, there is no information about the predicate devices input range. However, based on the DC offset of the predicate device, we **assume** it to be 960mV, to cater for handling this DC offset. Since the X-Trodes device is AC coupled, it has no need to digitize all this vast DC range and ADC conversion is applied only on the AC signal.

A typical adult human ECG signal, which is about 5mV amplitude. It constitutes a portion of about 5mV/960mV (0.0166) of the assumed input range. This portion practically utilizes only 17 bits out of its 24-bit resolution, according to the following calculation:

Quantization step is 960,000µV/(2^24-1)= 0.057µV.

Digital representation of 5mV would be 5000µV/0.057µV= 87,381 (binary 1 0101 0101 0101 0101) which is 17 bits.

FDA has also cleared many ECG devices that have a 16-bit resolution.

Lastly, the results of the clinical study presented in Section 20 of the Original 510(k) submission demonstrate that the quality of the EEG/ECG/EOG/EMG waveforms is sufficient for clinical purposes. Taken together, these considerations are sufficient to demonstrate that the X-trodes device is substantially equivalent to the predicates in this aspect.

3. Sampling frequency (Rate)

Sampling rate should be considered in conjunction with the frequency response and should be at least 220% of the max sampled frequency to practically comply with Nyquist's law of digitation.

Therefore, the discussion should be whether the device has sufficient sampling rate to cover its frequency range. The X-Trodes device has a frequency range of 750Hz, which is broader than the predicate device's (350Hz). This frequency range can be accommodated by a sampling rate of 1,650Hz. Therefore, the X-Trodes device's sampling rate of 4KHz exceeds the required sampling rate and qualifies as substantially equivalent in this aspect.

In addition, the results of the clinical study presented in Section 20 of the Original 510(k) submission demonstrate that the quality of the EEG/ECG/EOG/EMG waveforms is sufficient for clinical purposes. Taken together, these considerations are sufficient to demonstrate that the X-trodes device is substantially equivalent to the predicates in this aspect.

4. Input impedance

The input impedance of the X-Trodes device complies with clause 201.12.4.103 of the IEC60601-2-25 ECG standard which states that "The input impedance shall be at least 2,5 MΩ within a d.c. offset voltage range of ±300 mV".

In addition, FDA has cleared EEG devices such as the Digital NeuroPort Biopotential Signal Processing System(K202174) that also have an input impedance of ≥10 MΩ.

Lastly, the results of the clinical study presented in Section 20 of the Original 510(k) submission demonstrate that the quality of the EEG/ECG/EOG/EMG waveforms is sufficient for clinical purposes. Taken together, these considerations are sufficient to demonstrate that the X-trodes device is substantially equivalent to the predicates in this aspect.

5. DC offset

The X-Trodes device is **AC coupled,** thus its DC offset limits are derived from the OV/UV protection devices which are set at +3.0v and –1V. This DC offset range is broader than the predicate's DC offset range, rendering the XTR system more tolerant to DC offset, thus the X-trodes device is substantially equivalent in this aspect.

6. Noise

For ECG, the X-trodes device's noise is smaller than the predicate device's, thus constitutes substantial equivalence.

For EEG, the X-trodes device's noise is slightly higher than the predicate device, however it relates to only a portion of the EEG spectrum. Furthermore, the overall noise performance over the **full EEG spectrum** of the X-trodes device, complies with the IEC60601-2-26 EEG standard as shown in the Bench Test Report.

For EMG, the X-trodes device's noise is slightly higher than the predicate device's, however, it was demonstrated in the clinical trial that the measured EMG signal was of the required signal quality. Moreover, since there is no standard noise requirement for EMG, and since EMG signal's dynamic input range is similar to ECG, compliance with ECG noise standard can fulfill this requirement. The X-Trodes device complies with ECG noise requirement of 30 µV peak-to-valley referred to the input (IEC60601-2-25). Therefore, the X-Trodes device is substantially equivalent in this aspect.

7. CMRR

The X-Trodes device CMRR complies with the applicable provisions for both- IEC60601-2-26 EEG and IEC60601-2-25 ECG standards of CMRR > 90db, which constitutes adequate performance.

Conclusion

In conclusion, the subject X-trodes device has the same intended use as the proposed predicate devices, that is to acquire and display electrophysiological data. While there are technological differences, these differences do not raise different questions of safety and effectiveness, and therefore the predicate devices can serve as predicate devices for the X-trodes 510(k).

10. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The only patient-contacting component of the X-trodes System M is the XTR Electrode patches. The X-trodes System M is classified as a surface medical device, in contact with intact skin for less than 24 hours. The following biocompatibility testing was conducted:

- Sensitization, ISO 10993-10:2021
- Irritation, ISO 10993-23:2021
- Cytotoxicity, ISO 10993-5:2009

Electrical Safety

The following tests were conducted:

IEC 60601-1:2005 (3rd ed) + CORR. 1:2006 + CORR.2:2007+A1:2012, *Medical electrical equipment: Part 1: General requirements for basic safety and essential performance*, including US deviations

IEC 62133-2:2017, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 60601-2-25:2011, *Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*

ISO/IEC 80601-2-26:2019, *Particular requirements for the basic safety and essential performance of electroencephalographs*

IEC 60601-2-40:2016, *Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment*

Electromagnetic Compatibility (EMC)

The following tests were conducted:

AAMI TIR69:2017, *Risk management of radio-frequency wireless coexistence for medical devices and systems*

ANSI/IEEE C63.27:2017, *Evaluation of Wireless Coexistence*

IEC 60601-1-2:2014+A1:2020/Ed. 4.1, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests*

Software

Software was evaluated for a moderate level of concern as recommended in the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

IEC 60601-1-6:2020, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

Human factors testing in accordance with the FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*.

11. SUMMARY OF CLINICAL TESTING

X-trodes conducted a study to evaluate the accuracy and consistency of the X-trodes System M compared to an FDA-cleared clinical electrophysiology device.

Methods: X-trodes conducted a case-controlled study of 55 subjects who wore the subject and reference devices (X8) simultaneously. The test duration was approximately 20 minutes and was conducted in a clinic environment. There was a one minute preliminary screening evaluation to determine that electrode conductivity was established and then four minutes of data collection for each modality. Study subjects were adults who had been referred by either a neurologist or a cardiologist for an electrophysiology test in the last 5 years.

Results: The primary study endpoint was the proportion of interpretable readings of each ExG signal by the XTR that are equivalent to those of the reference device. The agreement proportion for the ECG was 89.36%, for the EEG 97.37%, for the EMG 96.15% and for the EOG 95.24%. All lower 98.75% confidence intervals are higher than 60%. Taking into consideration the high agreement proportions per signal modality and the high CI, it can be concluded that the primary end point was met successfully.

For the secondary end point, each modality, the characteristic signal was quantified, and the RMS values were obtained by comparing the signals captured by the X-trodes and X8 devices. The results demonstrate the consistency and reliability of the measurements obtained from the devices and provide an indication of the level of agreement between them.

Conclusions: The comparison between the X-trodes XTR and the predicate device demonstrates that the XTR satisfied the pre-specified performance criteria and thus can be found substantially equivalent to the X8 sleep profiler PSG.

12. CONCLUSION

The results of the performance testing described above demonstrate that the X-trodes System is as safe and effective as the predicate device and supports a determination of substantial equivalence.