May 20, 2021

CGX, LLC
℅ Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K203331
Trade/Device Name: Quick-20m
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: Class II
Product Code: GWL, GXY
Dated: May 4, 2021
Received: May 5, 2021

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

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)*
K203331

Device Name
Quick-20m

Indications for Use *(Describe)*
The Quick-20m is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.

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

Submitter:	CGX, LLC
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Email:	Spencer@CGXSystems.com

Date prepared:	June 23, 2020
Trade name:	Quick-20m
Common name:	Physiological Signal Amplifier
Product Code, Primary:	GWL, GXY
Regulation:	21 CFR 882.1835

Substantial equivalence claimed to: g.tec medical engineering GmbH g.Nautilus PRO, K171669, a Class II device.

Device Description:

The Quick-20m is a wireless, battery-operated 10-20 montage EEG headset utilizing dry sensor technology. The headset provides an integrated approach to the wireless acquisition of EEG signals. A seated patient is free to exhibit natural movements while real-time data is collected. The Quick-20m includes advanced amplification and shielding to reject ambient electrical noise.

The headset obtains high-quality EEG with minimal scalp preparation. Patented mechanisms and a range of replaceable dry sensors align to various head shapes and sizes, maintaining sensor positions in a standard 10-20 layout. EEG channels are digitized with 24 bits of resolution at 500 Hz. The Quick-20m is suitable for general-purpose EEG.

Principle of Operation

The Quick-20m headset is a wireless physiological signal amplifier that integrates cutaneous electrodes in a 10-20 montage. The headset captures EEG from the electrodes with 24 bits of resolution at 500 Hz, amplifies the signal and sends the data to a computer for further analysis by a healthcare professional.

The environment of use for this device is in a home or healthcare facility setting, such as a doctor's office. The device is not sterile.

The CGX Quick-20m works in the same manner as the predicate device, the g.tec medical engineering GmbH g.Nautilus PRO (K171669), with no safety concerns.

Intended Use(s)

The CGX Quick-20m is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.

Technological Characteristics

The CGX Quick-20m is substantially equivalent to the predicate device, the g.tec medical engineering GmbH g.Nautilus PRO for wireless transmission of EEG to a computer. It utilizes dry sensors on 20 monopolar channels to acquire EEG data via a headset worn on the head and transmits this data, via 24-bit Delta-Sigma A/D conversion at a sampling rate of 500 Hz/channel, wirelessly to a computer. The Quick-20m is battery powered with exactly the same CMRR, noise and power-on LED indicators as the predicate. The CGX Quick-20m meets all the applicable safety standards as the predicate, as listed in the Substantial Equivalence Table below with the same system components, patient connections/inputs and firmware/driver software as the predicate.

Item	**CGX Quick-20m This Submission**	**g.tec medical engineering GmbH g.Nautilus PRO**	**Substantial Equivalence Comments**
Intended Use	The Quick-20m is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer	The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer	Same as predicate

EEG/Polygraphic Channels	20 monopolar channels. Electrode grid is standard 10-20 layout	Up to 32 monopolar channels, different electrode grids available providing 8, 16 or 32 channels and 32 or 16 channels CSP layout on predefined positions	Fewer maximum number of channels but equivalent in safety and effectiveness
DC Channel	All	All	Same as predicate
Full Scale Input Range	± 300 mV	± 187.5 mV to ± 2.25 V	Fixed range but equivalent in safety and effectiveness
A/D Conversion	24-Bit Delta-Sigma	24 Bit Delta-Sigma	Same as predicate
Sampling Rate	500 Hz/channel	User selectable (250, 500 Hz/channel)	Similar to predicate but equivalent in safety and effectiveness
CMRR	>90 dB at 60 Hz	>90 dB at 60 Hz	Same as predicate
Noise	<0.6 µV RMS, 1-30 Hz	<0.6 µV RMS	Same as predicate
Power Supply	Battery, 3.0 V DC (Two 1.5 V AAA)	Battery, 3.7 V DC	Different battery chemistry but equivalent in safety and effectiveness
Rated Power Consumption	0.3 VA	0.5 VA	Less power consumption but equivalent in safety and effectiveness
Amplifier-PC Interface	Wireless to receiver, USB to computer	Wireless to receiver, USB to computer	Same as predicate
Other Interfaces	Power on LED	Power on LED	Same as predicate
Use Standard Sensors And Electrodes	Electrodes are included (Ag/AgCl) - Commercially available sensors	Electrodes and cap are included (Ag/AgCl or golden dry electrodes, elastic cap with certain electrode positions)	Similar to predicate but equivalent in safety and effectiveness

Dimension	20 (L) x 18 (W) x 19 (H) cm	80 (L) x 60 (W) x 27 (H) mm	Larger dimensions but similar in safety and effectiveness
Weight	<600 g	<200 g	More weight but equivalent in safety and effectiveness
Isolation	wireless, patient isolation	wireless, patient isolation	Same as predicate
System Components	Amplifier/Digitization/ Electrodes/Cap Charging Device + USB cable Receiver + USB cable	Amplifier/Digitization/ Electrodes/Cap Charging Device + USB cable Receiver + USB cable	Same as predicate
Firmware / Driver Software	Resident	Resident / CD	Same as predicate
Digital Inputs/Outputs	16 inputs, all patient separated, no outputs	8 inputs, all patient separated, no outputs	More digital inputs but equivalent in safety and effectiveness
Stimulation Unit Input/Output	Not available	Not available	Same as predicate
Patient Connection And Inputs	Receiver: USB - 1 connector DIGITAL IN - 1 connector	Receiver: USB - 1 connector DIGITAL IN - 1 connector	Same as predicate
Type Of Applied Part	BF	BF	Same as predicate
Impedance Measurement	Performed with 125 Hz	Performed with 10 Hz	Impedance check performed at different frequency but similar in safety and effectiveness
Input Impedance	>100 MOhm	>100 MOhm	Same as predicate

Filters	DC up to 131 Hz	DC up to 200 Hz (depending on sampling frequency)	Fewer digital filters but equivalent in safety and effectiveness
Frequency Response	Linear between 0.1 and 100 Hz	Linear between 0.1 and 100 Hz	Same as predicate
Environment Of Use	Electrophysiological	Electrophysiological	Same as predicate
Where Used	On the head	On the head	Same as predicate
Number Of Possible Electrodes	20 Channels in standard 10-20 head map	Different electrode grids available providing 8, 16 or 32 channels and 32 or 16 channel CSP layout on predefined positions	Fewer number of possible electrodes but equivalent in safety and effectiveness
Size Of Caps	One size for adults: 52-62 cm	Various for infants, children (mini, midi, maxi) and adults (small, medium, large), head circumference: 32-62 cm	Smaller range of sizes but equivalent in safety and effectiveness
Style Of Caps	Cap is full mechanical headset	Full head cap	Different style of construction but similar in safety and effectiveness
Performance Requirements	Needs to transmit electrophysiological signals from an individual to data collection device	Needs to transmit electrophysiological signals from an individual to data collection device	Same as predicate
Cap Material	HP Multi-Jet Fusion PA11 and PA12	Oeko-Tex certificate	Other material but equivalent in safety and effectiveness
Biocompatibility Testing On Patient Contact Materials	Evaluation done	Evaluation done	Same as predicate

Type Of Electrodes	Active dry	Active, wet and dry	Same as predicate for dry
Reprocessing	Cleaning of all components with isopropyl based wipes	Cleaning with multistage enzymatic cleaner of cap and wet electrodes Disinfection of cap and wet electrodes with low level disinfectant based on Glucoprotamin Cleaning of dry electrodes with cleaning wipe Disinfection of dry electrodes with disinfection wipe	Similar reprocessing but equivalent in safety and effectiveness
Safety Standards	IEC 60601-1 / AAMI ANSI ES60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 80601-2-26 IEC 60601-2-40 (not applicable) ISO 14971 IEC 62304 / AAMI ANSI IEC 62304 AAMI ANSI ISO 10993-1 AAMI ANSI IEC 62366 IEEE 2010-2012	IEC 60601-1 / AAMI ANSI ES60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 60601-2-40 ISO 14971 IEC 62304 / AAMI ANSI IEC 62304 AAMI ANSI ISO 10993-1 AAMI ANSI IEC 62366 IEEE 2010-2012	Similar to predicate but equivalent in safety and effectiveness

Substantial Equivalence Discussion

The CGX Quick-20m is substantially equivalent to the g.Nautilus PRO based on indications for use and comparison of functional and technological characteristics. Both devices are intended to provide the healthcare professional with an electroencephalogram (EEG) and transmit this data wirelessly to a computer. Both products fit on the head, utilize dry sensors and have the same amplifier/PC interface.

The minor differences between the CGX Quick-20m and the g.Nautilus PRO do not raise new safety or effectiveness concerns or questions. These differences are discussed below and in the substantial equivalence table.

The CGX Quick-20m is slightly larger than the g.Nautilus PRO (predicate), has slightly less input range (+/- 300 mV), a 500 Hz/channel sampling rate versus the user selectable sampling rate of 250 or 500 Hz/channel on the predicate, a battery chemistry of 3.0V DC versus the 3.7V DC of the predicate, and consumes slightly less power than the predicate. None of the aforementioned differences impact safety nor effectiveness. Further, the g.Nautilus PRO (predicate) offers both wet and dry sensors, while the Quick-20m offers dry sensors.

The CGX Quick-20m device was evaluated by a third party (Intertek) for all applicable safety standards and passed without anomalies.

Further, the company completed human factors and usability evaluation according to applicable versions of IEC 62366 and applicable FDA guidance, and the device demonstrated usability across sizes and positioning, resulting in quality, usable EEG data.

Specifically, the human factors usability program consisted of three components. An In-Field Human Factors test, six published academic studies, and service and repair data.

Bench testing on the Quick-20m includes Intertek certifications to 80601-2-26 and 60601-2-26, in addition to internal company design verification testing that successfully demonstrated compliance to user inputs, and in accordance with 21 CFR 820.40. Clinical testing on the Quick-20m was not applicable.

Animal Studies

This submission does not require nor include data on animal testing.

Clinical Studies

Clinical studies were not required to demonstrate that this device is as effective and at least as safe as the predicate device.

Conclusion:

CGX has been commercializing this EEG technology for research purposes (i.e. not clinical use) since 2015 and in over tens of thousands of uses there have been no safety related customer complaints or quality concerns. This customer experience was leveraged as the platform for the development of the medical device version - the CGX Quick-20m.

A majority of the characteristics of the CGX Quick-20m are identical to those of the g.Nautilus PRO (predicate). The minor differences discussed above and in the Substantial Equivalence Table raise no safety concerns and do not impact effectiveness of the acquisition of EEG. The CGX Quick-20m performs as effectively as the predicate device for the same intended use with no safety concerns.