January 24, 2020

g.tec medical engineering GmbH
Christoph Guger
CEO
Sierningerstrasse 14
4521 Schiedlberg, Austria

Re: K191432
Trade/Device Name: cortiQ PRO
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU, GWL, OLT
Dated: December 18, 2019
Received: December 23, 2019

Dear Christoph Guger:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191432

Device Name
cortiQ PRO

Indications for Use *(Describe)*
The system is intended to statistically evaluate brain activity reflected in a broad band of high-gamma frequencies in the human electroencephalogram (EEG). These measures should always be interpreted in conjunction with review of the original EEG waveform.

cortiQ PRO is intended for the evaluation of intracranial EEG recorded with the g.HIamp.

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

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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Date:	May 24, 2019

807.92(a)(2)

Trade Name:	cortiQ PRO
Common Name:	Normalizing quantitative electroencephalograph software Amplifier, physiological signal
Classification name:	Electroencephalograph 21 CFR section 882.1400
Product Code:	OLU, OLT, GWL

807.92(a)(3)

Predicate Device(s)

K#	K041263 (primary predicate)	K123255 (secondary predicate)
Trade/Device Name	NeuroGuide Analysis System	g.HIamp
Regulation Number	21 CFR 882.1400	21 CFR 882.1835
Regulation Name	Electroencephalograph	Physiological signal amplifier
Regulatory Class	Class II	Class II
Product Code	OLU	GWL
Date Received	July 20,2004 July 22,2004	October 10, 2012 October 18, 2012
Aspect	Signal analysis and statistical processing of data	Recording of EEG data and providing it to the signal processing via an application programming interface

807.92(a)(4)

Device Description

cortiQ PRO is a system that uses g.HIamp to map high-gamma broad band brain activity while running an experimental paradigm. The software helps to identify electrode positions coding differences in brain activity by means of experimental paradigm. cortiQ PRO performs the signal analysis in real-time and compares the high-gamma broad band activity during specific tasks. Then it performs a statistical analysis and visualizes electrodes coding the information that are statistically significant. It is abstracted from technical details of data acquisition, channel order and signal processing assuring robust and efficient measurements.

cortiQ PRO reads in the digital data from the g.HIamp amplification system (1200 Hz sampling frequency, up to 256 channels) via USB into the processing computer. The data is acquired without bandpass and notch filtering and without bipolar derivation. The software allows one to select the channels that should be acquired and stores the raw data together with header information for later off-line analysis.

Raw data is visualized on a raw data scope to inspect the data quality. The scope allows scaling of the data in amplitude and time. Furthermore the software allows scaling of all the channels to the same amplitude to make the interpretation easier. In the scope, it is possible to select a new ground and reference channel and to exclude a channel from the processing (if the data quality is bad). The raw data scope filters the data with a high-pass filter to remove DC-offsets for optimal visualization.

cortiQ PRO allows the operator to select an experimental paradigm that instructs the patient to perform certain tasks. The instructions are presented on a patient computer screen or are given via a speaker. The user can select, start and terminate the experimental paradigm. Additionally, the number of repetitions can be selected. A dedicated paradigm editor creates new paradigm files or modifies existing paradigms.

The rapid cortical mapping functions perform a common average reference (CAR) of all the active channels to remove common mode signals such as power line interference. Then the module calculates the high-gamma activity in certain frequency ranges for the different tasks and compares the high-gamma activity to those of another task according to the selected paradigm. Then a statistical analysis is performed and significant activation is plotted as bubble on the defined electrode position in order to identify important regions. When the mapping has ended, cortiQ PRO automatically generates a mapping report containing the montage definition, the paradigm definition, and the mapping results. This report is stored as pdf and can be printed. The mapping result is also stored for later analysis.

cortiQ PRO allows the operator to define montage definition files in the montage creator by loading predefined electrode grids from different manufacturers. Each grid has a certain number of channels. The montage creator allows the operator to assign a patient's name and date of birth, and a montage name to each file. Furthermore, it allows the operator to assign a grid name to each electrode grid. The grids can be placed on different background images to make the location interpretation easier. Electrodes from a grid can be disabled, enabled, used as reference or as ground electrodes. The grids can be resized or rotated. The montage creator assigns also the electrode grids automatically to the amplifier inputs channels and creates a report with the channel definition. The results can be stored to be modified later. The report is stored as pdf and can be printed.

cortiQ PRO comes with an installer that installs the software under Windows. A hardlock is required to start the mapping software.
The mapping system comes with Instructions for use and a training program.

807.92(1)(5)

Intended Use(s)

The system is intended to statistically evaluate brain activity reflected in a broad band of high-gamma frequencies in the human electroencephalogram (EEG). These measures should always be interpreted in conjunction with review of the original EEG waveform.

cortiQ PRO is intended for the evaluation of intracranial EEG recorded with the g.HIamp.

807.92(a)(6)

Technological Characteristics

System relevant comparison characteristics between cortiQ PRO system and the two predicates g.HIamp and NeuroGuide Analysis System:
Table I

	Item	cortiQ PRO	g.HIamp K123255	NeuroGuide Analysis System (NeuroGuide Base, NeuroStat, Neurofeedback) K041263	Comment
1.	Intended Use	The system is intended to statistically evaluate brain activity reflected in a broad band of high-gamma frequencies in the human electroencephalogram (EEG). These measures should always be interpreted in conjunction with review of the original EEG waveform. cortiQ PRO is intended for the evaluation of intracranial EEG recorded with the g.HIamp.	The g.Hlamp amplifier is intended to be used to acquire biopotentials and transmit them to a computer via the USB port connection. These biopotentials include for example electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG).	For clinical use the NeuroGuide Analysis system is to be used by qualified medical or clinical professionals for the statistical evaluation of the human electroencephalogram (EEG)	cortiQ PRO combines both intended uses and limits it to the statistical evaluation of brain activity and is therefore equivalent in safety and effectiveness.
2.	Contraindication / Limitations	• The device must not be used directly on the heart. • The device must not be used for the determination of brain death. Additional examinations are needed for diagnosis and no diagnosis may be done only based on using this device. • The device must not be used during defibrillation. Remove all electrodes and probes from the patient before defibrillation, otherwise the operator may receive an electrical shock or the connected instrument may be damaged. • The device must not be used in humans with pace-makers or electrical stimulators • Must not be used for electromyography (EMG), electrooculography (EOG), electrocardiography (ECG) • The device must be used either by a medical expert, such as a medical doctor with expertise in the field of neurology or neurosurgery, or by a medical technical expert such as neuroscience specialists. A user is only eligible to operate the device after completed device training. • The device must not be used when a patient is non-compliant to planned procedures due to age, cognitive function, or cognitive development stage. Such procedures might depend on the active cooperation of the patient and/or a sufficiently developed brain, and/or other aspects. Generally	• The device must not be used directly on the heart. • The device must not be used for the determination of brain death. Additional examinations are needed for diagnosis and no diagnosis may be done only based on using this device. • The device is not protected against the effect of cardiac defibrillator discharge • The device must not be used in humans with pace-makers or electrical stimulators	Only for qualified medical clinical professionals.	cortiQ PRO shows additional limitations and contraindications but is equivalent in safety and effectiveness.

		patients that are eligible for brain surgery in general and the individual type of surgery (e.g. epilepsy, tumor, or similar) in particular are also eligible for the usage of this device. In the individual case the responsible surgeon has to decide upon the procedures and the usage of the device. • The device must not be used for diagnosis without validation by another modality. The device must not be used for patient monitoring.			
3.	System components	• g.HIamp including: - amplifier - AC/DC adapter - USB cable - 1-4 electrode connector boxes. - driver software • personal computer inclusive speakers and monitor • additional monitor including USB cable • cortiQ PRO software • hardlock USB dongle	• g.HIamp including: - amplifier - AC/DC adapter - USB cable - 1-4 electrode connector boxes. - driver software	• software • personal computer • amplifier • additional monitor	cortiQ PRO includes also a processing computer and screen for paradigm presentation, but is equivalent in safety and effectiveness.
4.	Safety standards	IEC60601-1 IEC60601-1-2 IEC60601-2-26 ISO 14971 IEC 62304 IEC 62366	IEC60601-1 IEC60601-1-2 IEC60601-2-25 IEC60601-2-26 IEC60601-2-40 MDD 93/42/EEC IEC60601-1-4 ISO 14971 IEC 62304	No remark in 510k summary or instruction for use	cortiQ PRO covers the required standards to ensure equivalence in safety and effectiveness.
5.	Dimensions	• standard personal computer • g.HIamp:197 (L) x 197 (W) x 90 (H) mm • additional monitor	197 (L) x 197 (W) x 90 (H) mm	• personal computer • amplifier • additional monitor	cortiQ PRO is equivalent in safety and effectiveness.
6.	Weight	• g.HIamp 1.875kg • personal computer • additional monitor	1.875kg	• personal computer • amplifier • additional monitor	cortiQ PRO is equivalent in safety and effectiveness.
7.	Software/ Firmware	Firmware resident on g.HIamp, g.HIamp API on personal computer, cortiQ software on personal computer.	Firmware resident on g.HIamp, g.HIamp API on personal computer,	Only software on personal computer	cortiQ PRO uses both resident firmware and software components but is equivalent in safety and effectiveness.
8.	User interface	GUI	g.HIamp API	GUI	cortiQ PRO uses a graphical user interface (GUI) and is therefore equivalent in safety and effectiveness.

Comparison between cortiQ PRO and g.HIamp characteristics for data acquisition:
Table II

	Item	**cortiQ PRO**	**g.HIamp K123255**	**Comment**
9.	EEG/Polygraphic channels	80-256 monopolar	80-256 monopolar	Same as predicate.
10.	DC channel	80-256	80-256	Same as predicate.
11.	Full scale input range	± 250 mV	± 250 mV	Same as predicate.
12.	A/D conversion	24 Bit SAR	24 Bit SAR	Same as predicate.
13.	Sampling rate	User selectable (256, … up to 38400 Hz/channel) predefined in setting 1200 Hz	User selectable (256, … up to 38400 Hz/channel)	Preselected for cortiQ PRO system but equivalent in safety and effectiveness.
14.	Noise	<0.5 µV RMS, <2 µV peak-to-peak	<0.5 µV RMS, <2 µV peak-to-peak	Same as predicate.
15.	Power Supply	External IEC 601-1 mains adapter, 5V DC	External IEC 601-1 mains adapter, 5V DC	Same as predicate.
16.	Internal Storage	N/A Optional on PC HDD	N/A	cortiQ PRO allows signal data storage on the controlling computer but is equivalent in safety and effectiveness.
17.	Amplifier-PC Interface	USB	USB	Same as predicate.
18.	Other Interfaces	Power on LED	Power on LED	Same as predicate.
19.	Use standard sensors and electrodes	Yes (electrodes and sensors are not included with the amplifier)	Yes (electrodes and sensors are not included with the amplifier)	Same as predicate.
20.	Isolation	Opto coupler, patient isolation CF type	Opto coupler, patient isolation CF type	Same as predicate.
21.	Digital inputs/outputs	16 inputs, all patient separated, no outputs	16 inputs, all patient separated, no outputs	Same as predicate.
22.	Patient connection and device inputs	80-256 monopolar inputs – 80-256 plugs 4 ground inputs – 4 plugs USB – 1 connector DIGITAL IN – 2 connectors HOLD – 1 connector 1 x USB – screen 1 x USB - hardlock	80-256 monopolar inputs – 80-256 plugs 4 ground inputs – 4 plugs USB – 1 connector DIGITAL IN – 2 connectors HOLD – 1 connector	Additional connectors of personal computer in the cortiQ PRO system but equivalent in safety and effectiveness.
23.	Type of applied part	CF	CF	Same as predicate.
24.	Impedance measurement	Possible on hardware but disable in software.	Performed with 10 Hz	No impedance measurement in cortiQ PRO but equivalent in safety and effectiveness.
25.	Input impedance	>100 MOhm	>100 MOhm	Same as predicate.
26.	Filters in the amplifier	DC up to 2000 Hz (depending on sampling frequency). DC used in preset.	DC up to 2000 Hz (depending on sampling frequency)	cortiQ PRO records data without applied hardware filter but is equivalent in safety and effectiveness.
27.	Frequency response	Linear between 0.1 and 170 Hz	Linear between 0.1 and 100 Hz	Same as predicate.

Comparison between cortiQ PRO and NeuroStat characteristics for statistical analysis:
Table III

	Item	**cortiQ PRO**	**NeuroGuide Analysis System (NeuroStat) K 041263**	**Comment**
28.	Signal processing	Real-time	Post-hoc	cortiQ PRO performs the analysis in real-time but is equivalent in safety and effectiveness.
29.	Signal source	g.HIamp API	Imported from a data-file	The cortiQ PRO directly gets data from the g.HIamp API so it increases the effectiveness but is equivalent in safety.
30.	Band power estimation	Auto regressive model for power spectrum (AR)	Fast Fourier transformation (FFT) for power spectrum	cortiQ PRO uses an AR model for optimized data processing but is equivalent in safety and effectiveness.
31.	Statistical analysis	Parametric statistical test with R^2 output metric	ANOVA (Analysis of variances)	cortiQ PRO uses R^2 values for statistical analysis and NeuroStat ANOVA but is equivalent in safety and effectiveness.
32.	Analysis output	R^2 value for each channel	p-value for each channel	coritQ PRO uses R^2 values as output of analysis and NeuroStat p-values but is equivalent in safety and effectiveness.
33.	Visualization	Topographical mapping	Topographical mapping	Same as predicate
34.	Comparison of data segments	Comparison of baseline with task related data	Pre- and post-treatment data	cortiQ PRO performs the comparison within the same measurement but is safer and equivalent in effectiveness.
35.	Type of comparison	In-person comparison	In -person comparison, or group comparison	cortiQ PRO only provides in-person comparison but is equivalent in safety and effectiveness.
36.	Acceptance or reject of the results	Dependent upon the judgement of the clinician	Dependent upon the judgement of the clinician	Same as predicate.

Comparison between cortiQ PRO and Neurofeedback add-on characteristics for patient interaction:
Table IV

	Item	**cortiQ PRO**	**NeuroGuide Analysis System (Neurofeedback) K 041263**	**Comment**
37.	Visual feedback or interaction with patient	via additional monitor and paradigm presenter	via additional monitor and paradigm presenter	Same as predicate
38.	Auditory feedback or interaction with patient	via personal computer speakers and player	via personal computer speakers and player	Same as predicate
39.	Session setup	Paradigm editor for session setup.	Editor for session setup.	Same as predicate
40.	Number of runs	Freely adjustable	Freely adjustable	Same as predicate
41.	Run duration	Freely adjustable with limitation warning.	Freely adjustable	cortiQ PRO informs user when limits are underwent but is equivalent in safety and effectiveness.

807.92(b)(1)

cortiQ PRO was subject to safety and performance testing procedures. cortiQ PRO was tested with several real electrocorticographic (ECoG) and artificial test signals. While ECoG data contain task-related differences in the high-gamma frequency band, the artificial test data consists of dedicated noisy sinusoidal waveforms in the gamma range with lower amplitude in the task baseline interval (represents subject at pause) and higher amplitude in the action interval (represents subject doing a task) on all channels. The testing showed that the difference in gamma activity can be correctly mapped to correct electrode channels.
The testing showed that the system cortiQ PRO works like the predicate devices. In cortiQ PRO the medical safety is realized by using the g.HIamp which is powered by a medical grade power supply unit and provides isolated input and outputs for communication as well as appropriate isolated applied parts for the treatment.
Usability validation testing was performed in N=15 participants from the intended user group (neuroscientists, neurosurgeons, and neurologists). Participants in the usability validation testing performed simulated use testing following the specified device training program. The results of the usability testing demonstrate that the cortiQ PRO system (including the control software) meets all specified usability requirements at an acceptable risk level.
Testing of the cortiQ PRO was performed in compliance with the g.tec design control process.

807.92(b)(2)

Not applicable

807.92(b)(3)

Based on the comparison information in the technical comparison chart above and confirmed by verification/validation testing in compliance with design control requirements, cortiQ PRO was shown to be equivalent in safety and effectiveness to the predicate devices.