May 4, 2018

g.tec medical engineering GmbH
% Olaf Teichert
Responsible Third Party Official
TUV SUD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K173684
Trade/Device Name: g.Estim PRO
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical electrode
Regulatory Class: Class II
Product Code: GYC
Dated: April 20, 2018
Received: April 25, 2018

Dear Olaf Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173684

Device Name
g.Estim PRO

Indications for Use *(Describe)*
The g.Estim PRO is intended for functional brain mapping via electrical stimulation prior to cortical resections in the vicinity of essential cortex. The device must be used by medically trained and qualified personnel within a medical environment.

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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Contact Person: Christoph Guger

Date: 14th November 2016

807.92(a)(2)

Trade Name: g.Estim PRO

Common Name: Cortical Stimulator

Classification Names(s): Cortical Electrode
(per 21 CFR section 21 CFR 882.1310)

Product Code: GYC

807.92(a)(3)

Predicate Device(s)

Chatten Associates	S12X	K082629

807.92(a)(4)

Device Description

The g.Estim PRO is a neural, constant current, monophasic/biphasic stimulator for electrical stimulation of the brain (cortical stimulator). The device is battery supplied and can be controlled via USB from a computer. It can be trigged via software or with external devices and can provide beside the stimulation pulse also trigger signals for other devices.

The system consists of the stimulator, a USB connector cable to connect the device to a host computer, trigger out cables and trigger in cables, the driver and software package (including a graphical user interface and communication interface). Additionally the device can be triggered with a hand switch and/or foot switch.

The stimulator can be programmed and is a constant-current stimulator that can deliver electrical pulses with alternating polarities, lengths, amplitudes or trains of such pulses. The device is connected via USB to a computer and on the computer stimulator settings can be performed. On the computer a graphical user interface allows to perform all settings required for the stimulator. The stimulator is battery powered and has an optical isolation from the computer for safety reasons. A LED shows the stimulus time point.

The stimulator allows to send trigger pulses to external devices to synchronize the stimulus e.g. with EEG data acquisition devices. Such a trigger pulse can be programmed to occur prior to the stimulus so that e.g. a switching unit can switch before the stimulus occurs and can last longer than the electrical pulse to switch back after the pulse. Furthermore the triggers can be perfectly aligned with the stimulus so that an accurate trigger signal can be sent to the external device. The trigger lines are TTL compatible. Two trigger lines are supported.

The stimulus can be triggered via the software running on the computer or via external inputs to the stimulator. Important is that the stimulus is triggered very accurately for perfect synchronization. A foot switch or hand switch can be used to trigger the stimulator. The trigger input is TTL compatible. One trigger line is supported.

The device can perform an impedance measurement to check the electrodes impedance before the stimulation is done and can measure the actual stimulation current when a stimulation is done. The results are shown in the graphical user interface and can be passed also to other applications via an interface. The impedance measurement is done quickly so that the stimulation can rapidly be performed. If a high impedance is detected the stimulator does not stimulate.

g.Estim PRO works in the same manner as the approved and predicate device.

807.92(1)(5)

Intended Use(s)

The g.Estim PRO is intended for functional brain mapping via electrical stimulation prior to cortical resections in the vicinity of essential cortex. The device must be used by medically trained and qualified personnel within a medical environment.

807.92(a)(6)

Technological Characteristics

	Item	Chatten Associates S12X K082629	g.tec medical engineering GmbH g.Estim PRO This Submission	Comments
1.	Intended use	The S12X Cortical stimulator is intended for Intraoperative cortical stimulation mapping to aid in cortical resections in the vicinity of essential cortex. The ESAx option is intended for use with the S1 2X for facilitating the switching of the patient electrodes.	The g.Estim PRO is intended for functional brain mapping via electrical stimulation prior to cortical resections in the vicinity of essential cortex.	Reduced intended used, no switching unit option realized, but equivalent in safety and effectiveness
2.	User	The device is intended for use only by medically trained and qualified personnel, with a hospital or medical environment.	The device must be used by medically trained and qualified personnel within a medical environment.	Same as predicate
3.	Constant type	Constant current bi-phasic, rectangular	Constant current, bi-phasic, rectangular	Same as predicate
4.	Maximum stimulation charge	20 µC	15 µC	Lower limit for additional safety but equivalent in effectiveness.
5.	Pulse polarity	Selectable, positive, negative or alternating stimulus polarity on successive pulses	Selectable, positive, negative or alternating stimulus polarity on successive pulses	Same as predicate
6.	Train duration	0.2 to 20 sec in 7 steps	0.1 to 20 sec.	Shorter minimum train duration but equivalent in safety and effectiveness.
7.	Pulse amplitude	0.2 - 15 mA (peak), constant current, 17 steps	0.05 – 15 mA (peak), constant current, 0.01 mA increments	Allows lower start value, lower increments, but equivalent in safety and effectiveness.
8.	Stimulation frequency	2 – 100 Hz in 7 steps	2– 100 Hz, 0,1 Hz steps	Same frequency range and smaller increments for more flexibility, but equivalent in safety and effectiveness.
9.	Stimulation pulse duration	0.1 – 1.0 ms per phase (15 mA max); up to 2 ms per phase (10 mA max)	0.1 ms – 1 ms per phase	1 ms is long enough to achieve the necessary stimulation, but equivalent in safety and effectiveness.
10.	Max. transient voltage	34V, Zener Diode for hardware safety	80V, lead off via software for safety	Higher voltage for smaller electrode sizes but equivalent

				in safety and effectiveness.
11.	Power supply	12V DC, External medical power supply	Battery, 2 x 9 V	Battery supply to reduce risk and noise.
12.	Electrode size	Warning that electrodes with less than 4 sq mm can cause tissue damage.	Electrode size defines the safety threshold for stimulation parameters.	The g.Estim PRO is safe also with smaller electrode size, because the stimulator calculates the maximum stimulation current depending on electrode size. So equivalent in safety and effectiveness.
13.	Supported electrodes	Strip, grids, handheld probe	Strip, grids, handheld probe	Same as predicate
14.	Stimulus switching unit	Yes	No	Just a cortical stimulator for 1 bipolar channel, but equivalent in safety and effectiveness.
15.	Use standard sensors and electrodes	Electrodes are not included	Electrodes are not included	Same as predicate
16.	User input	Stylus (touch), standard mouse	Standard computer	Standard computer, but equivalent in safety and effectiveness.
17.	Graphical user interface	LCD	LCD display of computer	Same as predicate
18.	Simulator parameters setting	Through displayed controls	Through displayed controls	Same as predicate
19.	Active stimulation LED	Yes	Yes	Same as predicate
20.	Actual current delivered displayed	Yes	Yes	Same as predicate
21.	Dimension	337 x 165 x 178 mm	240 x 137 x 80 mm	Smaller and therefore easier to handle, but equivalent in safety and effectiveness.
22.	Weight	2.25 kg	0.85 kg	Lighter and therefore easier to carry, but equivalent in safety and effectiveness.
23.	Trigger out for external devices	Yes	Yes	Same as predicate
24.	Digital input	Isolated	Isolated	Same as predicate
25.	Patient isolation	BF	BF	Same as predicate
26.	Safety standards	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2 IEC60601-2-40 ISO14971 IEC62304 IEC62366	More standards applied.

27.	System components	Stimulator Switching array Hand controller Touchscreen Stylus Power Supply Portable carry case Cable to switching array Cable to manual probe	Stimulator with USB cable - Hand switch and foot switch - - Portable carry case - - 1 x Trigger in cable 2 x Trigger out cable	g.Estim PRO does not provide a switching array, Touchscreen Stylus and power supply, additionally with foot switch and trigger cables. Equivalent in safety and effectiveness.
28.	Firmware / software	Resident firmware	Resident firmware inside g.Estim PRO API/GUI on computer	Additional Front-end driver to operate but equivalent in safety and effectiveness.
29.	Log file	YES on device transferred with USB flash stick	YES on computer	Not saved, on device, but equivalent in safety and effectiveness.
30.	Digital inputs/outputs	1 external trigger input (disabled) 1 train duration out 1 trigger out (pulse)	1 trigger input (disabled) 1 pulse output 1 pulse output to trigger external devices	Programmable outputs but equivalent in safety and effectiveness.
31.	Connectors, switches	1 handheld controller connector 1 handheld probe connector 1 output connector to switching unit 2 USB 1 external trigger input 1 train duration output 1 trigger out(pulse) 1 DC power in 1 Ethernet connector 1 on/off switch 1 HW all stop switch 1 HW stimulation switch	1 hand/foot switch connector 2 safety sockets to connect electrodes - 1 USB connector DIO – 1 input connector DIO – 1 output connector 1 DIO – 1 output connector 2 2 battery housings - 1 on/off switch - -	Different in output for the switching unit, reduced connectivity with one USB and no Ethernet connector and no HW-switches , but equivalent in safety and effectiveness.
32.	Impedance measurement	Yes	Yes	Same as predicate
33.	Isolated power out	Yes	No	No isolated power out but equal in safety and effectiveness.
34.	Embedded controller	1	2	One additional to ensure the equal safety and effectiveness.

807.92(b)(1)

The stimulator was tested with a data acquisition device and provides rectangular stimulation pulses with the necessary frequency and amplitude range. Furthermore digital outputs were tested to provide trigger signals and digital inputs were tested to trigger the stimulation. The impedance measurement was tested with test impedances. The tests show that the stimulator works like the predicate device.
In g.Estim PRO medical safety is realized by isolating the applied part optically for data transmission via USB and by battery supply. The current for the impedance measurement is limited with resistors.

807.92(b)(2)
Not applicable

807.92(b)(3)
The conclusion is that g.Estim PRO and the predicate device provide electrical stimuli with varying pulse width, frequency and amplitude in the same way and that the stimulator is working substantial equivalent and as effective as the marketed device. g.Estim PRO is using battery supply and optical separated USB transmission and is therefore considered to be safe.