DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 5, 2017

g.tec medical engineering GmbH
% Alexander Schapovalov
Responsible Third Party Official
TÜV SÜD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K171669
Trade/Device Name: g.Nautilus PRO
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GXY
Dated: June 5, 2017
Received: June 5, 2017

Dear Mr. Schapovalov:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171669

Device Name
g.Nautilus PRO

Indications for Use *(Describe)*
The g.Nautilus PRO 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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K171669
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: 25th September 2015

807.92(1)(2)

Trade Name: g.Nautilus PRO

Common Name: Physiological Signal Amplifier

Classification Names(s): Physiological Signal Amplifier
(per 21 CFR section 21 CFR 882.1835)
Cutaneous Electrode
(per 21 CFR section 21 CFR 882.1320)

Product Codes: GWL, GXY

807.92(a)(3)

Predicate Device(s)

g.tec medical engineering GmbH	g.HIamp	K123255
Electro-cap International Inc.	Electro-Cap System	K112319

807.92(a)(4)

Device Description

g.Nautilus PRO is g.tec's bio-potential amplifier with wireless data transmission technology. The device allows the acquisition of up to 32 EEG (Electroencephalogram) channels with 24 bit resolution. The sampling frequency can be set up to 250 or 500 Hz. g.Nautilus PRO is available with 8-32 channels.
The wireless amplifier is transmitting data to a PC or notebook with 2.4 GHz technology. On the computer a receiver unit is connected with USB. Up to 32 analog to digital converters perform the simultaneous sampling. The sampling frequency can be set to 250 Hz or 500 Hz. Each analog to digital converter is operating with 1.024 MHz and performs a 2048 times oversampling for 500 Hz. A sampling frequency of 250 Hz yields to an over-sampling rate of 4096 with a very high signal to noise ratio. Furthermore, the device has an internal impedance check unit. g.Nautilus PRO works with either active gel or active dry electrodes and comes with an EEG cap with chin-strap. The device is controlled via its driver and application programming interface (API), which is part of the g.tec device service g.NEEDaccess. The device is battery supplied.

The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer. It captures the data, converts it into digital form and passes it on to a host computer running appropriate software. The device can be used for adults, children and infants. The host computer must use Microsoft Windows. g.Nautilus PRO comes with a C Application Programming Interface (C API) which allows to control the device.

The system consists of the charging device, the g.Nautilus PRO Headset (the amplification and digitization unit with EEG electrodes, cap and chin-strap), the receiver unit (with USB connector cable to connect the device to a host computer), the driver and the C API software.

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

807.92(1)(5)

Intended Use(s)

The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.

807.92(a)(6)

Technological Characteristics

Item	**g.tec medical engineering GmbH g.HIamp K123255**	**g.tec medical engineering GmbH g.Nautilus PRO This Submission**	**Substantial Equivalence Comments**
Intended Use	The g.HIamp 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 the electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG).	The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.	Similar to predicate in measuring EEG but equivalent in safety and effectiveness
EEG/Polygraphic channels	Up to 256 monopolar	Up to 32 monopolar channels. Different electrode grids available providing 8, 16 or 32 channels and 32 or 16 channel CSP layout on predefined positions	Less maximum amount of channels but equivalent in safety and effectiveness
DC channel	All	All	Same as predicate
Full scale input range	± 250 mV	± 187.5 mV to ± 2.25 V	Configurable full scale input range but equivalent in safety and effectiveness
A/D conversion	24 Bit SAR	24 Bit Delta-Sigma	Other A/D technique but equivalent in safety and effectiveness
Sampling rate	User selectable (256, … up to 38400 Hz/channel)	User selectable (250, 500 Hz/channel)	Less maximum sampling rate but equivalent in safety and effectiveness
CMRR	>90 dB at 60 Hz	>90 dB at 60 Hz	Same as predicate
Noise	<0.5 µV RMS	<0.6 µV RMS	Higher RMS noise but equivalent in safety and effectiveness
Power Supply	External IEC 601-1 mains adapter, 5V DC	Battery, 3.7 V DC	Other power supply but equivalent in safety and effectiveness
Rated power consumption	20 VA	0.5 VA	Less power consumption but equivalent in safety and effectiveness
Internal Storage	N/A	N/A	Same as predicate
Amplifier-PC Interface	USB	Wireless to receiver, USB to computer	Other technique of data transfer but equivalent in safety and effectiveness
Other Interfaces	Power on LED	Power on LED	Same as predicate
Use standard sensors and electrodes	Electrodes and sensors are not included with the amplifier	Electrodes and cap are included (Ag/AgCl or golden dry electrodes, elastic cap with certain electrode positions)	Electrodes are dedicated to device and therefore better in safety and effectiveness
Dimension	197 (L) x 197 (W) x 90 (H) mm	80 (L) x 60 (W) x 27 (H) mm	Smaller dimensions

			but equivalent in safety and effectiveness
Weight	1,875 kg	<200 g	Lighter weight but equivalent in safety and effectiveness
Isolation	Opto coupler, patient isolation CF type	wireless, patient isolation BF type	Only BF applied part but equivalent in safety and effectiveness considering the intended use
Safety standards	IEC60601-1 IEC60601-1-2 IEC60601-2-25 IEC60601-2-26 IEC60601-2-40 IEC60601-1-4 ISO 14971 IEC 62304	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 considering the intended use
System Components	Amplifier/Digitization AC/DC Adapter USB cable Electrode connector box and connector cable	Amplifier/Digitization/Electrodes/Cap Charging Device + USB cable Receiver + USB cable	Different system components but equivalent in safety and effectiveness
Firmware / driver software	Resident / CD	Resident / CD	Same as predicate
Digital inputs/outputs	16 inputs, all patient separated, no outputs	8 inputs, all patient separated, no outputs	Less digital inputs but equivalent in safety and effectiveness
Stimulation unit input/output	Not available	Not available	Same as predicate
Patient connection and inputs	256 monopolar inputs – 256 plugs 4 ground inputs – 4 plugs USB – 1 connector DIGITAL IN – 2 connectors HOLD – 1 connector	Receiver: USB – 1 connector DIGITAL IN – 1 connector	No connectors at the applied part and therefore better in safety and effectiveness
Type of applied part	CF	BF	Only BF applied part but equivalent in safety and effectiveness considering the intended use
Impedance measurement	Performed with 10 Hz	Performed with 10 Hz	Same as predicate
Input impedance	>100 MOhm	>100 MOhm	Same as predicate
Filters	DC up to 2000 Hz (depending on sampling frequency)	DC up to 200 Hz (depending on sampling frequency)	Less 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

Item	**Electro-cap International Inc. Electro-cap System K112319**	**g.tec medical engineering GmbH g.Nautilus PRO This Submission**	**Substantial Equivalence Comments**
Intended Use	The Electro-cap is intended for	The g.Nautilus PRO is intended to	Not intended for

	use in routine clinical settings where rapid placement of a number of EEG electrodes is desired	be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.	clinicla settings but equivalent in safety and effectiveness
Environment of Use	Electrophysiological	Electrophysiological	Same as predicate
Where Used	On the head	On the head	Same as predicate
Number of possible electrodes	2-256	Different electrode grids available providing 8, 16 or 32 channels and 32 or 16 channel CSP layout on predefined positions	Less number of possible electrodes but equivalent in safety and effectiveness
Size of caps	Various: extra-small to large, head circumference 26-66 cm (adults, children, infants)	Various for infants, children (mini, midi, maxi) and adults (small, medium, large), head circumference: 32-62 cm	Similar sizes but equivalent in safety and effectiveness
Style of caps	Full head cap	Full head cap	Same as predicate
Ear slits	Yes	Yes	Same as predicate
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
Manufacturing method cap	Caps sewn	Caps sewn	Same as predicate
Electrode metal	Gold plated or Ag/AgCl	Gold plated or Ag/AgCl	Same as predicate
Cap material	Spandex	Oeko-Tex certificate	Similar material but equivalent in safety and effectiveness
Electrode mounts	Polyethylene	POM-C	Other material but equivalent in safety and effectiveness
Location of wiring	Inside cap	Outside cap	Other location of wiring but equivalent in safety and effectiveness
Cable length	3-5 feet	Up to 25 cm	Shorter cable length but equivalent in safety and effectiveness
Type of cables	Standard ribbon cable and lead wires	Flex-print, material polyimide	Other type of cables but equivalent in safety and effectiveness
Type of electrode connector	D-Sub connector	No connector. Cables go directly into amplifier	No connector and therefor better in safety and effectiveness
Biocompatibility testing	None was conducted	Evaluation done	Better in safety and effectiveness
Type of electrodes	Passive, wet	Active, wet and dry	Better in safety and effectiveness
Reprocessing	Low level disinfection with IVORY® or PALMOLIVE®. Sterilization possible via cold sterilizing solution or cold gas sterilization process	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 better in safety and effectiveness

The g.HIamp 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 the electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG). The Electro-cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired. Therefore, if the Electro-cap is used together with g.HIamp building up a system, this system can be used to measure EEG as found in clinical settings.
The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.
Therefore both systems, g.HIamp with Electro-cap compared to g.Nautilus PRO, are intended to be used to measure EEG and transmit them to a computer. The difference in intended use applies only to the way of data transmission to a computer. g.HIamp with Electro-cap uses a USB cable connection whereas g.Nautilus PRO uses a wireless connection. In both cases the software on the computer indicates if data are lost, so the user can interpret the data correctly. Therefore the wireless connection of g.Nautilus PRO is safe and effective and substantial equivalent to the cable connection of the predicate device.

807.92(b)(1)
The amplifier was tested with an external signal generator which applies sinusoidal signals with different frequencies and amplitudes to the inputs of the amplifier. The correct signal transmission and amplification was determined with Bode plots for each channel. The impedance measurement was tested with test impedances. Noise was tested by short-cutting the input channels. The tests show that the signal quality is appropriate for EEG measurements and that impedance measurements are accurate.
In g.HIamp, medical safety is realized by isolating the applied part with digital isolators, DC/DC converters and by using a medical power supply unit. In g.Nautilus PRO the medical safety is realized with battery supply and wireless transmission of the data. In both cases the current for impedance measurement is limited to be safe.

807.92(b)(2)
Not applicable

807.92(b)(3)
The conclusion is that g.Nautilus PRO and the predicate device amplify sinusoidal signals with varying frequencies and amplitudes in the same way and that the amplifier is working substantial equivalent and as effective as the marketed device. g.Nautilus PRO is using battery supply and wireless transmission and is therefore considered to be safe. The electrodes are safe and effective because they are directly integrated into the device and have the necessary material and diameter.