K123255



# 510(k) Summary

DEC 20 2012

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: 5th June 2012

807.92(1)(2)

Trade Name: g.HIamp

Common Name: Physiological Signal Amplifier

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

Product Code: GWL

807.92(a)(3)

**Predicate Device(s)**

| | | |
|---|---|---|
| g.tec medical engineering GmbH | g.USBamp | K060803 |

807.92(a)(4)

## Device Description

The g.HIamp is a fully programmable system which provides a total of 256 analog input channels each of which can be configured, amplified and converted to digital form (analog to digital conversion). The applied part is digitally isolated. The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 601-1 requirements, which feeds in +5V DC. Internally, the +5V DC is further isolated by a dedicated DC/DC type converter.

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 electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG). 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, infants and animals. The host computer must use Microsoft Windows 7. g.HIamp comes a driver and with a C Application Programming Interface (C API) which allows to control the device.

The system consists of the AC/DC adapter (power supply unit), g.HIamp (the amplification and digitization unit), electrode connector boxes with cables to the g.HIamp (to connect EEG electrodes), a USB connector cable to connect the device to a host computer and the driver and C API software.

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

807.92(1)(5)

## Intended Use(s)

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 electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG).

807.92(a)(6)

## Technological Characteristics

| Item | g.tec medical engineering GmbH<br>g.HIamp<br>This Submission | g.tec medical engineering GmbH<br>g.USBamp<br>K060803 |
|---|---|---|
| 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 electroencephalogram (EEG), electromyogram (EMG), electrooculogram (EOG), and electrocardiogram (ECG). | Measuring, recording and analysis of electrical activity of the brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG. |
| EEG/Polygraphic channels | 256 monopolar | 16 monopolar |
| DC channel | 256 | 16 |
| Full scale input range | ± 250 mV | ± 250 mV |
| A/D conversion | 24 Bit SAR | 24 Bit Sigma-Delta |
| Sampling rate | User selectable (256, … up to 38400 Hz/channel) | User selectable (32, 64, 128, 256, ∴ up to 38400 Hz/channel) |
| CMRR | >90 dB at 60 Hz | >105 dB at 60 Hz |
| Noise | <0.5 µV RMS, <2 µV peak-to-peak | <0.35 µV RMS, <2 µV peak-to-peak |
| Power Supply | External IEC 601-1 mains adapter, 5V DC | External IEC 601-1 mains adapter, 5V DC |
| Rated power consumption | 20 VA | 7 VA |
| Internal Storage | N/A | N/A |
| Amplifier-PC Interface | USB | USB |
| Other Interfaces | Power on LED | Power on LED |
| 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) |
| Dimension | 197 (L) x 197 (W) x 90 (H) mm | 197 (L) x 155 (W) x 40 (H) mm |
| Weight | 1.875 kg | 1 kg |
| Isolation | Digital isolator, patient isolation CF type | Digital isolator, patient isolation CF type |
| Safety standards | IEC60601-1<br>IEC60601-1-2<br>IEC60601-2-25<br>IEC60601-2-26<br>IEC60601-2-40<br>MDD 93/42/EEC<br><br>IEC60601-1-4<br>ISO 14971<br>IEC 62304 | IEC60601-1<br>IEC60601-1-2<br>IEC60601-2-25<br>IEC60601-2-26<br>IEC60601-2-40<br>MDD 93/42/EEC<br><br>IEC60601-1-4<br>EN ISO 14971<br>ANSI/AAMI SW68:2001 |
| System Components | Amplifier/Digitization<br>AC/DC Adapter<br>USB cable<br>Electrode connector box and connector cable | Amplifier/Digitization<br>AC/DC Adapter<br>USB cable |
| Firmware | Resident | Resident |
| Digital inputs/outputs | 16 inputs, all patient separated, no outputs | 8 inputs, 4 outputs, all patient separated |
| Stimulation unit input/output | Not available | Not available |
| Patient connection and inputs | 256 monopolar inputs – 256 plugs<br>4 ground inputs – 4 plugs<br>USB – 1 connector<br>DIGITAL IN – 2 connectors<br>HOLD – 1 connector | 16 monopolar inputs – 16 plugs<br>4 reference inputs – 4 plugs<br>4 ground inputs – 4 plugs<br>USB – 1 connector<br>SYNC IN and SYNC OUT – 2 |

| | | |
|---|---|---|
| | | connectors<br>DIG I/O 1 and DIG I/O 2 – 2 connectors<br>SC (short-cut) – 1 connector |
| Type of applied part | CF | CF |
| Impedance measurement | Performed with 10 Hz, patient auxiliary current < 1 uA, hardware limited | Performed with 20 Hz, patient auxiliary current < 1 uA, hardware limited |
| Input impedance | >100 MOhm | >100 MOhm |
| Filters | DC up to 2000 Hz (depending on sampling frequency) | DC up to 2000 Hz (depending on sampling frequency) |
| Frequency response | Linear between 0.1 and 100 Hz | Linear between 0.1 and 100 Hz |

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 are determined with BODE diagrams 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 both devices g.HIamp and g.USBamp medical safety is realized by isolating the applied part with digital isolators, DC/DC converters and using a medical power supply unit. 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.HIamp 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.HIamp is using the same key components for medical safety as g.USBamp and is therefore considered to be safe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

g.tec medical engineering, GmbH
c/o TUV SUD America, Inc.
Mr. Alexander Schapovalov
1775 Old Highway 8, NW
New Brighton, MN 55112-1891

Re: K123255
Trade/Device Name: G.Hlamp
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: October 10, 2012
Received: October 18, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K123255

Device Name: g.Hlamp

Indications For Use:

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).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123255