K060803



MAY 2 2006

# 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: 1st December 2005

807.92(1)(2)

Trade Name: g.USBamp

Common Name: Physiological Signal Amplifier

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

Classification Number: GWL

807.92(a)(3)

**Predicate Device(s)**

| | | |
|---|---|---|
| Neuroscan | Nuamps | K023536 |

510(k) Summary
g.tec medical engineering GmbH
g.USBamp

807.92(a)(4)

## Device Description

The g.USBamp is a fully programmable system which provides a total of 16 analog input channels each of which can be configured, amplified and converted to digital form (analog to digital conversion). The applied part is optically 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.USBamp is intended to be used for measuring, recording and analysing 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. 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 XP. g.USBamp comes 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.USBamp (the amplification and digitization unit), a USB connector cable to connect the device to a host computer and the C API.

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

807.92(1)(5)

## Intended Use(s)

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.

510(k) Summary
g.tec medical engineering GmbH
g.USBamp

807.92(a)(6)

## Technological Characteristics

| **Item** | **g.tec medical engineering GmbH<br>g.USBamp<br>This Submission** | **Neuroscan<br>Nuamps<br>K023536** |
|---|---|---|
| Intended Use | 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. | The Neuroscan Nuamps is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical setting for EEG. Patient population: Adults, children and infants. |
| EEG/Polygraphic channels | 16 monopolar | 40 monopolar |
| DC channel | 16 | 40 |
| Full scale input range | ± 250 mV | ± 130 mV |
| A/D conversion | 24 Bit Sigma-Delta | 22 Bit Sigma-Delta |
| Sampling rate | User selectable (16, 32, 64, 128, 256, … up to 38400 Hz/channel) | Use selectable (125, 250, 500, 1000 Hz/channel) |
| CMRR | >105 dB at 60 Hz | 100 dB at 60 Hz |
| Noise | <0.35 µV RMS, <2 µV peak-to-peak | 0.7 µV RMS, 4 µV peak-to-peak |
| Power Supply | External IEC 601-1 mains adapter | From USB (5V) |
| Internal Storage | N/A | N/A |
| Amplifier-PC Interface | USB | USB |
| Other Interfaces | Power on LED | Power on LED,<br>16-letter LCD |
| 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 155 (W) x 40 (H) mm | 198 (L) x 151 (W) x 40 (H) mm |
| Weight | 1,55 kg | 0,695 kg |
| Isolation | Opto coupler, patient isolation CF type | Optical Signal Isolation |
| Safety standards | EN60601-1<br>EN60601-1-2<br>EN60601-2-25<br>EN60601-2-26<br>EN60601-2-40<br>MDD 93/42/EEC<br><br>EN60601-1-4<br>EN ISO 14971<br>ANSI/AAMI SW68:2001 | IEC 60601-1<br>IEC 60601-1-1<br>IEC 60601-1-2<br>IEC 60601-1-4<br>IEC 60601-2-26<br>EN 46001<br>EN ISO 9001 :2000<br>MDD 93/42/EEC<br>AAMI EC53-1995<br>CDRH Guidance Document on the "Performance Standard of Electrode Lead Wire and Patient Cables," March 9, 1998 |
| System Components | Amplifier/Digitization<br>AC/DC Adapter<br>USB cable | Amplifier/Digitization<br>USB cable |
| Firmware | Resident | Resident |
| Digital inputs/outputs | 3 inputs, 2 outputs, all patient separated | 14 inputs, 2 outputs, all patient separated |
| Stimulation unit input/output | Not available | 9 pin Sub-D connector |
| Patient connection and inputs | 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 | 40 monopolar inputs – 40 plugs<br>2 ground inputs – 2 plugs<br>USB – 1 plug<br>Sync.1 – 1 plug<br>Sync.2 – 1 plug<br>Trigger port – 9 pin Sub-D |

510(k) Summary
g.tec medical engineering GmbH
g.USBamp

| | DIG I/O – 1 connector<br>SC (short-cut) – 1 connector | |
|---|---|---|
| Type of applied part | CF | BF |
| Impedance measurement | Performed with 20 Hz | Performed with 30 Hz |
| Input impedance | $>10^{10}$ Ohm | >80 MOhm |
| Filters | DC up to 2000 Hz (depending on sampling frequency) | DC up to262 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.

807.92(b)(2)
Not applicable

807.92(b)(3)
Since g.USBamp and the predicate device amplify sinusoidal signals with varying frequencies and amplitudes in the same way the amplifier is working equivalent to the marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

g.tec medical engineering GmbH
c/o TUV Product Service
Mr. Stefan Preiss
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

MAY 2 2006

Re: K060803
Trade/Device Name: g.USBamp
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: April 11, 2006
Received: April 17, 2006

Dear Mr. Preiss:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 8 Statement of indications for use

510(k) Number (if known): K060803

Device Name: g.USBamp

Indications For Use:

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.

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 In Vitro Diagnostic Devices (OIVD)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060803