K111055

510(k) Summary

DEC 2 1 2011

Submitter

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Registration Number:

Will apply

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Preparation Date

December 21, 2011

Device

Trade Name:

Galaxy System

Classification Name: Standard polysomnograph with electroencephalograph
Regulation Number: 882.1400
Product Code: OLV
Device Class: Class II
Classification Panel: Neurology

Predicate Devices

Neurolink IP Model PK1117 by Natus Medical
Product code: GWQ
510(k) number: K100683

Alice 5 by Respironics
Product code :GWQ
510(k) number: K04059

Device Description

The **Galaxy** system (which includes the Jupiter amplifier and Galaxy software) is a Polysomnography System that is intended to acquire, record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders.

The system can record, monitor, store and transfer of up to 42 channels of biophysical parameters. Generally the device is capable of acquiring and displaying the following parameters:

- EEG
- EOG (eye movement)
- Chin EMG
- Leg EMG (leg movement)
- ECG (single channel)
- Chest respiratory effort
- Abdomen respiratory effort
- Nasal Flow Thermistor
- Nasal Flow Pressure
- Body position
- Snoring
- Oximeter
- Patient "Event" button

The components of the Galaxy system include:

1. Headbox/Amplifiers (i.e., "BrainBox EEG amplifier, "Touchproof connector box", "Jupiter amplifier") – Galaxy can support two amplifier/headbox models, 1166 and 1142. Both models are electrically exactly the same, except for the differences between the number of channels. Channel characteristics of each of the two available amplifiers are as follows:

	Model 1166	Model 1142
AC Channels (e.g., EEG, EOG, EMG, nasal flow pressure, body position, respiratory effort)	64	32
DC Channels (e.g., body position)	0	8
Oximetry and Event button connection	Yes	Yes
Total number of connectable electrodes/ sensors used for data collection	66	42
Number of grounds	2 (G1, G2 – for "common reference and ground"	2 (G1, G2 – for "common reference and ground"

2. Ethernet Interface – connects the power supply and IP connections with the amplifiers (through the "Isolator") for converting serial data of the amplifier to the Ethernet data of the PC.
3. Isolator (ISO101) – Isolates the AC power and Ethernet signals for patient safety.
4. Connecting Wires – the amplifiers and isolator are connected with a "BrainBus" serial interface; the Isolator and Ethernet Interface are connected with a "BrainNet Connector".
5. Desktop Computer – Receives the EEG data through the Ethernet and TCP/IP connection from the "Amplifier" and then stores and displays it to the user. It also serves as the user interface for the device (receiving and implementing commands from the user).
6. Electrodes – Third party electrodes and sensors such as surface electrodes compatible with 32 AC inputs by means of touch-proof connectors, "Nonin oximeter (XPOD3012)," and "respiratory effort sensors" can be used with the system, but these sensors are not provided with the device. Only sensors specifically tested and verified for use with the device should be used and are listed in the user's manual.

The interconnections of the components of the Amplifier are shown below:

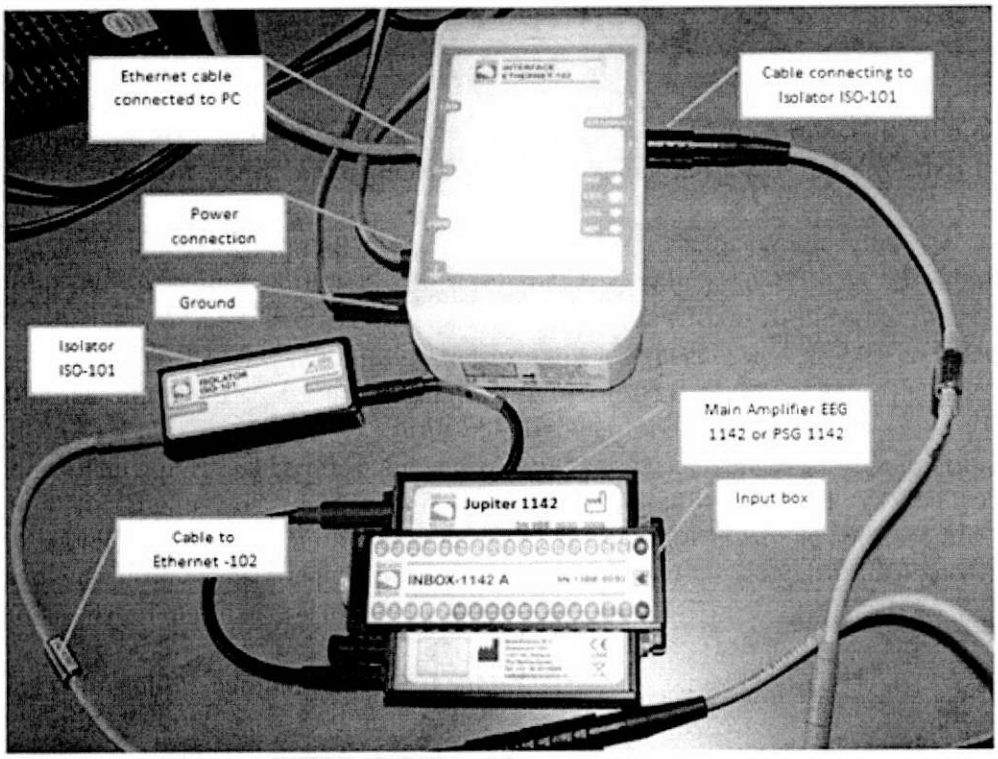

Figure 1: Jupiter Hardware Set-up

All the connections and functions are exactly similar to the predicate device Natus Neurolink IP 1117. The Galaxy software does not support the control of the flash unit and the digital I/O.

7. Galaxy Software – The Galaxy software's main functionalities include the following:
   a. Record and display signals - Collect and display PSG parameters. Plot acquired data on screen (within a time window of 30 seconds) and store on hard-disk of computer.

b. Provide tools for Manual Review of Data - Allow the user to review and manually analyze data, edit this analysis and delete the entered events if needed. Software also displays the user annotations along with the signal traces, as trend overview over the night and as a list, and allows the user to review the acquired data after the completion of the recording to examine and annotate afterwards (offline).

c. Generate Patient Reports – The software calculates summaries of the manually scored data and print them as tabulated reports and shows simple computer calculations like average value, rates etc...

Galaxy also has the following additional functions:

- changing the mode of the amplifier for calibration, impedance check or data acquisition
- sending commands to set sample rate of the digitization, to specify the recording montage and to receive data from the Jupiter amplifier via Ethernet interface.

A screen shot below shows the features of Galaxy.

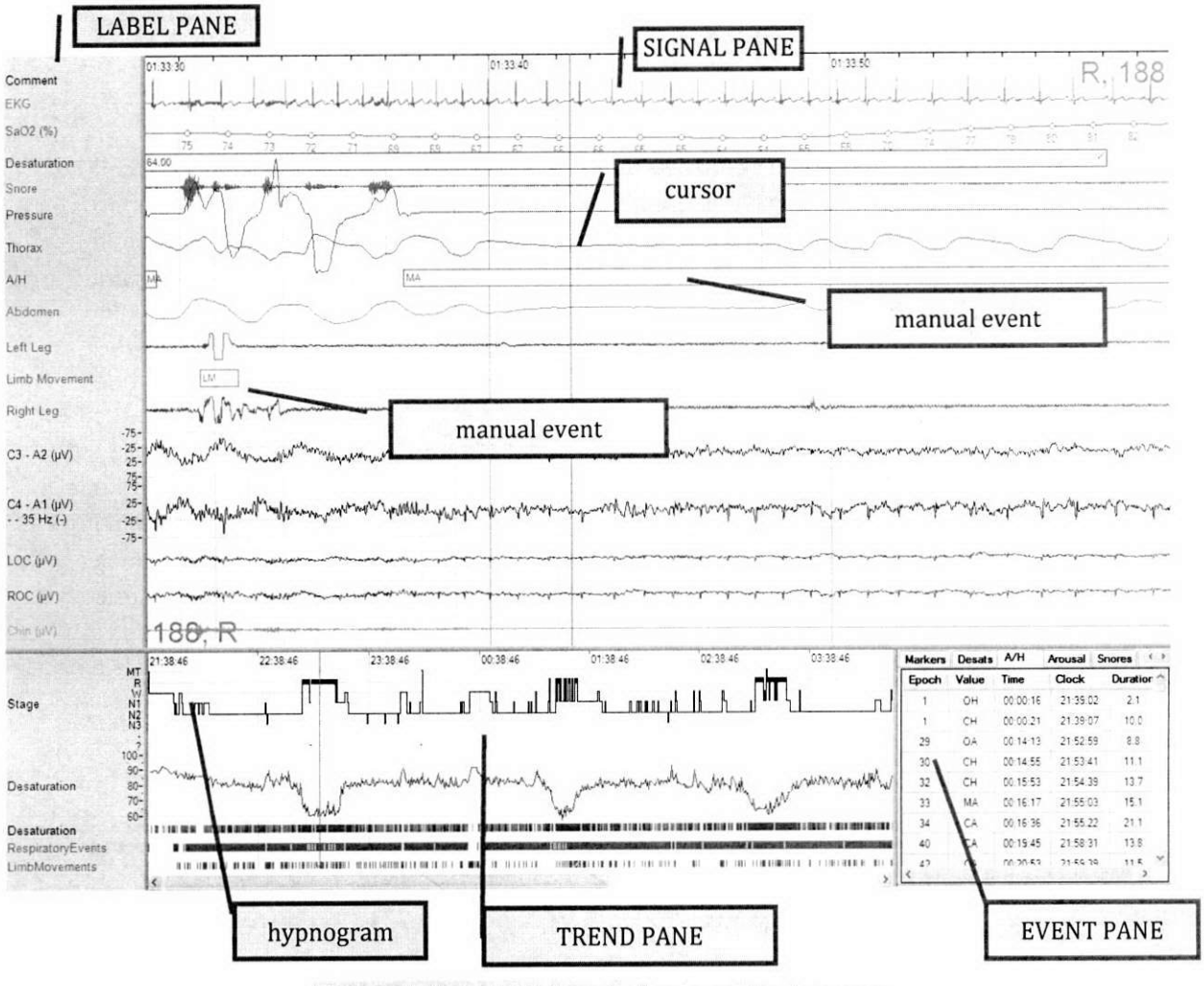

Figure 2: Sample Galaxy Software output screen

The device does not provide any automatic scoring algorithms.

Intended Use

The Galaxy System (which includes the Jupiter amplifier and Galaxy software) is intended for use as a polysomnographic system to acquire record, display, print and store physiological parameters to assist clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers, clinics or other test environments where adults or infants require the documentation of sleep or other physiological disorders. The Galaxy system does not provide alarms and is not intended for use as an automated apnea monitor.

Caution: Federal law restricts this device to sale by or on the order of a Physician.

Technological Characteristics

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. The items like Intended use, principle of operation, are compared. The summary of this comparison table demonstrates that the Galaxy System has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

Testing

The **Galaxy System** has been tested and verified in various phases, internal testing, verification and validation as well as external testing and validation.
The device passed verification and validation testing that includes tests for amplifier voltages and functioning, flash memory, pulse width specifications, impedance testing, channel outputs with and without input signals, noise, electrode grounding, and oximeter interface functionality.

The design was verified throughout the design process. Risk analysis was done, appropriate measures were implemented and their effectiveness verified. The external test house DARE was used to confirm compliance to EMC requirements.

Safety Tests have been performed to verify compliance with IEC 60601-1-1 and IEC 60601-2-26 to ensure that there are no potential hazards on patients, other persons, or the surroundings. Electromagnetic Compatibility tests according to IEC 60601-1-2 have been performed to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment. Immunity tests to IEC 60601-1-2 have been performed to ensure that the EEG equipment has the ability to operate satisfactorily in its electromagnetic environment.
The Galaxy system was tested for displaying and printing of signals and scoring. These tests were performed at the work-bench by developers, in the factory by developers and in the field by sleep-technicians and researchers. The standard ANSI/AAMI SW68: 2001 Medical Device Software - Software Life Cycle Processes was used as advisory standard for the development and testing of all software functions.

Substantial Equivalence Comparison Table

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
Device Classification	II	II	II
Product Code	OLV	GWQ	GWQ
Classification Panel	Neurology	Neurology	Neurology
Intended use	The Galaxy System(Software and Jupiter Amplifier) is intended for use as a polysomnographic system to acquire record, display, print and store physiological parameters to assist clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics or other test environments where adults or infants require the documentation of sleep or other physiological disorders. The Galaxy system does not provide alarms and is not intended for use as an automated apnea monitor. **Caution:** This device is to be used under the supervision of a physician.	The Alice 5 System is a Polysomnographic System that is intended to record, display, and print physiological parameters to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. The device does not provide alarms and is not intended for use as an automated apnea monitor. This device is to be used under the supervision of a physician.	Neurolink IP model PK1117 is intended to be used as an electroencephalograph to acquire, digitize and transmit electroencephalographic and other physiological signals (such as pulse and oximetry) for EEG in research and clinical environments. This device is to be used under the supervision of a physician.
Note	Electrophysiological characteristics of the Jupiter Amplifier are technically the same to both predicates. The software functions of Galaxy are functionally equivalent to Alice5.		
Warning	Do not use in conjunction with a defibrillator and stimulators. Do not use in conjunction with medical imaging devices	Not known	Do not use in conjunction with a defibrillator and stimulators. Do not use in conjunction with medical imaging devices.
Contra indications	This device does not provide alarms and is not intended for use as an automated apnea monitor. The software is not intended for use as a life-support equipment like vital signs monitoring	This device does not provide alarms and is not intended for use as an automated apnea monitor.	The device is not intended for use as a life support equipment such as vital signs monitoring in intensive care units

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
Prescription use	Yes	Yes	Yes
Contact of device with patient body	**None**	**None**	**None**
Environment	The device can be used in hospitals, institutions, sleep centers or other similar environments where patients require the documentation of various sleep or other physiological disorders.	The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders.	Neurolink can be used in hospital environment and clinics.
Environmental Conditions	Normal: +5 to +40°C, max 80% rH non-condensing, 700-1060hPa	Not known	Normal: +5 to +40°C, max 80% rH non-condensing, 700-1060hPa
Data input types	ECG, neurological, respiratory	ECG, neurological, respiratory	Neurological, othe physiological
No. of AC Channels	32 or 64 (neurological or physiological)	26 neurological, 10 physiological	64 neurological
AD sample rate	32,768	2000	32,768
Output Sample Rate	1024	2000	1024
Storage rate	1024	200	1024
Digital resolution	16bits	16bits	16bits
Oximeter channel	Yes	Yes	Yes
No. of DC Channels	8 (for patient safe sensors like body position) for 1142 model.	12	None
Connection to patient	By means of sensors like EEG, ECG, EMG electrodes to AC inputs In addition, some of the AC inputs are used to connect to external patient safe sensors like respiration	By means of sensors like EEG, ECG, EMG electrodes to AC inputs. In addition, some of the AC inputs are used to connect to external patient safe sensors like respiration.	By means of sensors like EEG, electrodes to AC inputs.
Connections for 42 channel amplifier	32 AC connections for EEG/EOG/EMG/ECG. Active sensors can be connected to AC channels	26AC channels for EEG/EOG/EMG/ECG. Active sensors can be connected to AC channels	Not applicable
	8 DC channels for other physiological sensors	10 DC channels for other physiological signals	-no-
	Oximeter	Oximeter	Oximeter
	Event	Event	Event
Connections for 64 AC channel	64 AC connections for EEG/EOG/EMG/ECG. Active sensors can be connected to AC channels	Not Applicable	64 AC connections for EEG
	NO DC channels	Not Applicable	NO DC channels
	Oximeter	Oximeter	Oximeter
List of Components			

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
Main amplifier unit	JUPITER: Separate Brainbox EEG-1166 for 64channel AC, oximetery and event This can be used in neurological disorders during sleep.	None	Brainbox EEG1166 for 64 channel AC, oximetery and event
Main amplifier unit	Brainbox EEG1142 for 32 Channel AC and 8 Channel DC, oximetery and event	Base Station	Not supported
Patient connection box	1142 or 1166 input box	Patient headbox	1166 input box
Patient Isolation unit	ISO101	This function is in the Base StationPC	ISO101
Computer interface	Ethernet 102	This function is in the Base station	Ethernet 102
Power supply	AC-DC adapter	This function is in the Base Station	AC-DC adpater
Oximeter	Oximeter Nonin	In Patient Headbox	Oximeter Nonin
Electrode Check :	Same as PK1117	Yes	The impedance of the EEG electrodes can be tested under PC control.
Impedance Check level :	Same as PK1117	Yes, detailed specs not known	The electrode impedance check level can be selected in 6 steps: 5 - 10 - 20 - 50 - 100 and 200 K-Ohm. ± 20% accuracy.
Impedance check signal :	Same as PK1117	Yes, detailed specs not known	Sine wave of approx. 128 Hz. With a measuring current < 4 µA pk/pk.Duty cycle per electrode is 1/64.
Calibration	Variable freq. square wave, Calibration voltage and freq. under software control	1 Hz, 98mV square wave	Variable freq. square wave, Calibration voltage and freq. under software control
Input Bias Current	Same as PK1117	Detailed specs not known but satisfy the usual requirements	Less than 0.001 µA (1 nA).
Input Noise EEG Amps :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	Less than 1 µV rms. at a bandwidth of 1 - 70 Hz
Input Impedance EEG Amps :	Same as PK1117	1.66	10 Meg-Ohm ± 10 %
Max. input signal EEG Amps :	Same as PK1117	±3.3mV	10 mV pk/pk for undistorted output.
Sensitivity EEG Amps :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	The sensitivity of the EEG amplifier is: 11.73 mV for full scale of 16 bits, resulting in 65536 levels. One LSB step corresponds to approx. 0.17895 µV
Max. DC offset of electrodes :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	+ or -300 mV DC. At 300 mV DC, max. undistorted input is 8.4 mV pk/pk.

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
Accuracy of EEG sensitivity :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	Overall max. ± 3% error. The software in the PC should run a calibration cycle to correct the total sensitivity error.
Common mode rejection ratio	Same as PK117	not known	120dB
Bandwidth	Same as PK1117	0.32 Hz to 106Hz	0.15Hz-1500Hz. Effective filter bandwidth depends on the sample rate chosen to avoid Nyquist aliasing problem
High pass filter AC/EEG Amps :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	Fixed time constant of 1 second. (min.0.78 sec./max. 1.2 sec.)
Low pass filter AC/EEG Amps :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	1500 Hz. ± 15% (-3dB). The filter is 2nd order (-12dB/octave).
Nyquist Filter type :	Same as PK1117	Detailed specs not known but satisfy the usual requirements	Multisection decimating FIR equiripple with linear phase characteristic.
Nr. of sections :	Same as PK1117		3
Decimation ratio :	Same as PK1117		32
Passband frequency :	Same as PK1117		1/3 of the output sample rate.
Stopband frequency :	Same as PK1117		1/2 of the output sample rate.
Ripple in passband :	Same as PK1117		0.01 dB
Attenuation at 1/2 Sample Rate :	Same as PK1117		Better than 40 dB.
DC channels sample rate	1024		Not supplied
Input Impedance DC Amps	1 MΩ ± 10 %		Not supported
Low pass filter DC Amps :	70 Hz. ± 15% (-3dB). The filter is 1st order (-6dB/octave).		Not supported
Amplifier Option	1142 or 1166	None	4 Brainbox EEG1166 to measure 256 AC channel
Input Connection	Separate Inbox	Patient interface box	Separate Inbox-
Signal Calibration	Done by software, depends on the recording functions	Done by software - depends on recording functions	Done by software - depends on recording functions
Electrode impedance check	Yes	Yes	Yes
Multiple Electrode connection cable	Yes (optional)	No	Yes (optional)
Patient Isolation	BrainBox Isolation box ISO 101	Yes in Base station	BrainBox Isolation box ISO 101
Power Supply	External AC power with patient Isolation	Integrated in Base Station	External AC power with patient Isolation

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
PC connection cable	CAT5	CAT5	CAT5
Number of Patients monitored simultaneously	One per PC	One per PC	Not known
Portable design	Yes	Yes	Yes
Record signals	Yes	Yes	Yes
Monitoring	Yes	Yes	Yes
Display	Yes	Yes	Yes
Print	Yes	Yes	Yes
Capable of Data transfer for analysis and report generation	Yes	Yes	Yes
Computer configuration	Desktop or laptop computer	Desktop	Not defined, probably desktop
Operating system	Windows7 or Windows Vista	Windows	Not defined, probably Windows
Number of simultaneous patients	One per unit.	One per unit	One per unit
Data Analysis	Optional (Always present, but clinician may choose to use) **Note** only the analysis of user scored events and stages is provided	Optional(Always present, but clinician may choose to use)	Not applicable, Amplifier Only
Events marked and annotated by user			
	Sleep Stage	Yes	Not applicable, Amplifier Only
	Apnea	Yes	Not applicable, Amplifier Only
	Arousal	Yes	Not applicable, Amplifier Only
	Leg movements	Yes	Not applicable, Amplifier Only
	Desaturations	Yes	Not applicable, Amplifier Only
	Cardiac events	Yes	Not applicable, Amplifier Only
	Body Positions	Yes	Not applicable, Amplifier Only
	Nap Start Stop	Yes	Not applicable, Amplifier Only
	Sleep Onset, End of sleep	Yes	Not applicable, Amplifier Only
	Lights On off	Yes	Not applicable, Amplifier Only
	CPAP level	Yes	Not applicable, Amplifier Only
	User annotations	Yes	Not applicable, Amplifier Only

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	**K111055**	**K040595**	**K100683**
	Recording comments	Yes	Not applicable, Amplifier Only
Calculations done by the software and reported			
	Average value	Yes	Not applicable, Amplifier Only
	Count (total number)	Yes	Not applicable, Amplifier Only
	Index (number of events per hour sleep)	Yes	Not applicable, Amplifier Only
	Maximum value	Yes	Not applicable, Amplifier Only
	Minimum value	Yes	Not applicable, Amplifier Only
	Total duration of the events	Yes	Not applicable, Amplifier Only
	Total duration of the events divided by time range	Yes	Not applicable, Amplifier Only
	Standard deviation of the mean duration of the events	Yes	Not applicable, Amplifier Only
	Latency to the occurrence of an event or a stage	Yes	Not applicable, Amplifier Only
Report	Optional (Always present, but clinician may choose to use)	Optional (Always present, but clinician may choose to use)	Not applicable, Amplifier Only
Data file format	EDF, or Galaxy Standard	Alice Standard or EDF	Not applicable, Amplifier Only
Annotation on study	Yes	Yes	Not applicable, Amplifier Only
Study modes	Recording, monitoring, retrieval and display	Recording, long term monitoring, retrieval and display	Not applicable, Amplifier Only
Digital Video	Yes (optional)	Yes (optional)	Not applicable, Amplifier Only
Optional equipment	Printer, multiple displays	Printer	Not applicable, Amplifier Only
Support multiple displays	Yes	Not defined	Not applicable, Amplifier Only
Patient protection	Type of protection against electric shock: Class II Degree of protection against electric shock: No applied part		Type of protection against electric shock: Class II Degree of protection against electric shock: No applied part
	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.		Equipment not suitable for use in the presence of a flammable unaesthetic mixture with air or with oxygen or nitrous oxide.
Standards			
	Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)	IEC 60601-1: 1988 + Al: 1 991 + A2: 1995, Medical Electrical Equipment - Part 1: General Requirements for Safety	Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)

Characteristics	Galaxy	Alice 5	Neurolink IP Model PK 1117
510 (K) ID	K111055	K040595	K100683
	Medical Electrical Equipment part 1-1: General requirements for Safety - Collateral Standard Safety Requirements for Medical Electrical Systems adopted IEC 60601-1 2ed. (01)	IEC 60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility - Requirements and tests	Medical Electrical Equipment part 1-1: General requirements for Safety - Collateral Standard Safety Requirements for Medical Electrical Systems adopted IEC 60601-1 2ed. (01)
	EN60601-2:26:2003 Particular requirements for the safety of electroencephalographs	IEC 60601-2-26: 2002 Medical Electrical Equipment - Part 2-26: Particular requirements for the safety of electroencephalographs.	EN60601-2:26:2003 Particular requirements for the safety of electroencephalographs
	ANSI/AAMI SW68: 2001 Medical Device Software - Software Life Cycle Processes. **Used as advisory standard for software development**	ANSI/AAMI SW68: 2001 Medical Device Software - Software Life Cycle Processes	

Substantial Equivalence Conclusion:

A thorough comparison between the Galaxy System and the predicate devices is shown in a tabular form (see above table). All the characteristics that affect the safety and effectiveness of the polysomnographic system are compared and presented in a clear format. The hardware of the Galaxy System (Jupiter amplifier) is identical to that of the Neurolink IP by Natus Medical. Both of them are manufactured by Braintronics and hence are same in safety and effectiveness. They were tested for safety by CSA and TUV. All the third party sensors that are recommended to be used in the Galaxy System have prior 510(k) approval from FDA. Calibration, calibration check, electrode impedance check are done and tested. The specifications meet the requirements of the Draft FDA guidance for 510(k) content for Electroencephalograph Devices.

The predicate Neurolink IP is not only equivalent to Jupiter amplifier but it is also exactly the same hardware, except that Jupiter also supports a 42 channel version. The main differences are 32 AC(EEG/EOG/EMG, ECG etc.) channels in the 42 channel version instead of 64 AC channels. The 42 channel version also has 8 DC channels that are not available in the predicate device.

The Galaxy software resides on a PC just like the Alice 5 and has the same indications for use and characteristics. The functions of the Galaxy software are the same as the software of the predicate device. Neurolink IP uses similar software to collect, store and visualize signals. These functions are generic for all three devices.

From the comparison table and the discussion, it can be seen that the Galaxy System is the same in safety and effectiveness as the predicate devices.

Conclusion

The test results demonstrate that the Galaxy system meets its objective of being reliable, safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Personal Health Institute International
c/o Mr. Kumar Kulkarni
USA Contact
RTS, Inc.
263 Cedar Creek Drive
Battle Creek, MI 49015

DEC 2 1 2011

Re: K111055
Trade/Device Name: Galaxy System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV
Dated: November 30, 2011
Received: December 7, 2011

Dear Mr. Kulkarni:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Personal Health Institute international

510(k) Number (if known): K111055

Device Name: Galaxy System

Indications For Use:

The Galaxy System (which includes the Jupiter amplifier and Galaxy software) is intended for use as a polysomnographic system to acquire record, display, print and store physiological parameters to assist clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers, clinics or other test environments where adults or infants require the documentation of sleep or other physiological disorders. The Galaxy system does not provide alarms and is not intended for use as an automated apnea monitor.

Caution: Federal law restricts this device to sale by or on the order of a Physician.

Prescription Use ___**YES**____ AND/OR Over-The-Counter Use __**NO**____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) (Optional Format 3-10-98)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

John Grimes

510(k) Number K111055