



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 21 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.

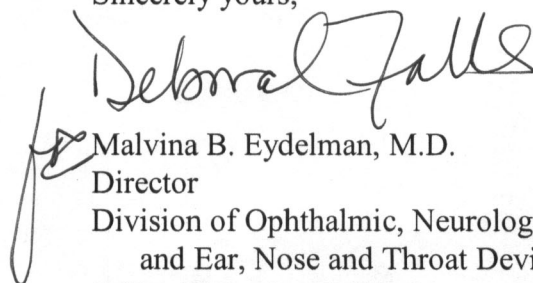
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

A handwritten signature in dark ink, appearing to read "Malvina B. Eydelman". The signature is fluid and cursive, with a large initial "M" and "E".

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