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

JUL - 9 2010

Galix Biomedical Instruments, Inc.
c/o Mr. Yoel Palomino
Technical Manager
2555 Collins Ave., C-5
Miami Beach, FL 33140

Re: K092853
Trade/Device Name: 3 Channel Digital Ambulatory ECG Recorder, GBI – 3SM
Regulatory Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph with Analysis Option
Regulatory Class: II (two)
Product Code: 74 MLO
Dated: June 2, 2010
Received: June 4, 2010

Dear Mr. Palomino:

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.

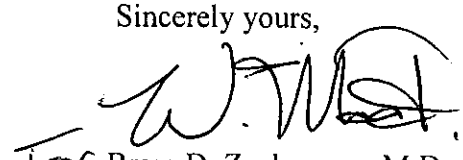
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GALIX BIOMEDICAL INSTRUMENTATION, INC.

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Indications for Use

510(k) Number: K092853/S1

Device Name: 3 CHANNEL DIGITAL AMBULATORY ECG RECORDER GBI - 3SM

Indications For Use: The primary use of ambulatory monitoring are listed below.

1 - Evaluation of suspected of known cardiac rhythm disorders.

2 - Evaluation of symptoms suggestive of an arrhythmia disorder.

3 - Holter recordings are also used to screen patients who have clinical syndromes in which the presence of an arrhythmia may increase the risk of sudden death.

4 - Patients who have suspected pacemaker malfunction may also require long term monitoring to document an intermittent episode of failure to capture or failures to sense.

5 - Evaluation of chest pain.

6 - Holter monitors are used in a serial fashion to judge the efficacy of antiarrhythmic drug treatment.

7 - The Galix GBI-3SM Digital Holter Recorder is intended primarily as a 24 hour ECG Ambulatory Holter Recorder. However the unit has the ability to record Very High Resolution ECG, at a sampling rate of 1000 samples per second.

The ECG data stored is then analyzed with the Late Potential Software.

Warning: The clinical significance of Late Potential measures should be determined by a qualified physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092853