DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Mr. Jordan Gavrielides
President
Galix Biomedical Instrumentation, Inc.
2555 Collins Avenue
Suite C-5
Miami Beach, FL 33140

Re: K971670
GBI-3S Ambulatory ECG Holter Recorder
Regulatory Class: II
Product Code: 74 DSH
Dated: January 5, 1998
Received: January 7, 1998

Dear Mr. Gavielides:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971610/A

510 (k) Number: K 971670

Device Name: 3 CHANNEL DIGITAL AMBULATORY ECG RECORDER

Indications for use:

Electrocardiographic recording to document a patient's arrhythmia has had widespread application as a non invasive tool in cardiology. A patient's arrhythmia may be documented by a simple electrocardiogram; however the use of techniques with longer monitoring periods, usually for 24 hours or more (Holter monitoring), increases the likelihood of documenting the arrhythmia. Since the original description by Dr Norman Holter in the 1950 s, Holter monitoring or continuous ambulatory electrocardiographic monitoring has been a useful technique for patients with cardiac arrhythmias.

Indications for Holter monitoring are listed in Table I. The primary use of ambulatory monitoring is for the evaluation of cases of suspected cardiac rhythm disturbances. Since these arrhythmias can be episodic, detection of complex ventricular arrhythmias will vary, depending of the duration of the recording.

A 24 - hour Holter recording permits the recording of cardiac rhythm during both sleep and awake states. Thus the variation of arrhythmias during waking hours and during physical and mental stress can be demonstrated.

Continue in page 2..

Concurrence of CDRH, Office of Device Evaluation (ODE)

W Zagorski MD

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971670

Presciption Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

510 (k) Number: K 971670

Device Name: 3 CHANNEL DIGITAL AMBULATORY ECG RECORDER

TABLE I: Indications for Holter monitoring

1 - Evaluation of suspected or known cardiac rhythm disorders.

2 - Evaluation of symptoms suggestive of an arrhythmia disorder.

3 - Evaluation of clinical syndromes in which arrhythmias may increase the risk of sudden death.

4 - Evaluation of pacemaker function.

5 - Evaluation of chest pain.

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

Holter monitors are frequently used as part of diagnostic studies to determine whether a new cardioactive drug has either antiarrhythmic or proarrhythmic effects. Because of spontaneous variability of a patient's arrhythmia these studies are often limited and should be viewed with caution.

Studies that have used longer monitoring periods may be more accurate.

Holter monitors may also be used for screening patients with symptoms suggestive of sinus node or AV node conduction problems.

Holter monitoring can be useful in correlating episodes of chest pain with diagnostic ST segment abnormalities.

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.

Such situations include the period after myocardial infarction, congestive heart failure and dilated cardiomyopathy, hypertrophic obstructive cardiomyopathy, and the congenital prolonged QT syndrome.

Holter recordings may also be useful in screening for arrhythmias in patients with the mitral valve prolapse syndrome and in those recovering from coronary artery bypass surgery.

Holter monitoring can also be used to screen patients with symptomatic or asymptomatic Wolff - Parkinson - White syndrome.

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Patients who have suspected pacemaker malfunction may also require long-term monitoring to document an intermittent episode of failure to capture or failure to sense. These abnormalities and oversensing problems may be easily documented during ambulatory monitoring.