JAN 26 1999

PaceArt Associates LK.P
HomeTrak Plus EASI Event Recorder System
510(k) Submission

510(k) Summary

(1) Submitter Information

Name: PaceArt Associates L.P.

Address: 22 Riverview Drive
Wayne, New Jersey 07470

Telephone Number: 973-696-3357

Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703
fax 201-727-1708
Date Prepared: June 8, 1998

(2) Name of Device:

Trade Name: HomeTrak Plus EASI Event Recorder System
Common Name: Cardiac Event Trans-Telephonic Recorder and Receiving System
Classification Name: Transmitters and Receivers, Electrocardiograph, Telephone (74DXH)

(3) Equivalent legally-marketed devices:

1. Braemar ER370, K923930
2. Paceart CPTS 86/12, K915632
3. Zymed 2010 Holter Analyzer, K955015 (analyzer only), K872781 (with EASI)
4. Totemite EASI system, K872781

(4) Description

The HomeTrak Plus Cardiac Twelve-Lead Event Recorder is a patient-activated ambulatory cardiac event monitor and associated central-station receiving equipment which are to be used for recording infrequent and elusive heart arrhythmias and transmitting them by telephone at a later time to a central analysis center. It records

three electrocardiographic leads and derives 12 electrocardiographic leads from the three transmitted. When the five electrodes are attached to the patient in the special configuration shown in the manual and the PaceArt WINCPTS central-station software with 12-lead option is used, the physician can either record a twelve-lead electrocardiogram or a three-lead electrocardiogram at the analysis center. The system for derivation of the 12-lead electrocardiogram from the five-electrode recording is called the "EASI" system. There are two elements to the Home Trak Plus system: a "looping" cardiac event recorder, and a special central-station program.

(5) Intended Use

The HomeTrak Plus Cardiac Twelve-Lead Event Recorder is a patient-activated ambulatory cardiac event monitor and associated central-station receiving equipment which are to be used for recording infrequent and elusive heart arrhythmias and transmitting them by telephone at a later time to a central analysis center, with the ability to record three electrocardiographic leads or to derive 12 electrocardiographic leads from the three transmitted.

(b) Performance data

(1) Non-clinical tests

The HomeTrak Plus event recorder has had standard electrical safety tests and been tested to EC38. The CPTS central station equipment has been also cleared by the FDA as a 12-lead ECG system (K915632), and meets the requirements for those devices.

The system was tested to show that electrocardiograms are operated on by the correct EASI coefficients.

The software has had extensive validity testing.

(2) Clinical tests

1. A series of patients had 12-lead electrocardiograms taken with the EASI predicate device and this system. The electrocardiograms were equivalent.
2. An electrocardiogram was taken with the HomeTrak Plus system and a Burdick 12-lead electrocardiograph. The recordings are equivalent.

(3) Conclusions

The HomeTrak Plus system is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1999

Dr. George Myers
PaceArt Associates L.P.
c/o Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K982090
PaceArt HomeTrak Plus EASI Event Recorder System
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: October 27, 1998
Received: October 29, 1998

Dear Dr. Myers:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

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510(k) Number (if known): K982090

Device Name: HomeTrak Plus EASI Event Recorder System

Indications for Use:

The HomeTrak Plus Cardiac Twelve-Lead Event Recorder is a patient-activated ambulatory cardiac event monitor and associated central-station receiving equipment which are to be used for recording infrequent and elusive heart arrhythmias and transmitting them by telephone at a later time to a central analysis center. It records three electrocardiographic leads and derives 12 electrocardiographic leads from the three transmitted, called the "EASI" system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982090