NOV 1 2 1997

Paceart Associates LP
510(k) Submission
Paceart Heart Access Plus Event Recorder
510(K) Summary

(1) Submitter Information:

Name: Paceart Associates LP.
Address: 22 Riverview Drive, Wayne New Jersey 07470
Telephone Number: 973-696-1122
Contact Person: Dr. George Myers, 201-727-1703

(2) Names:

Trade: Paceart Heart Access Plus Event Recorder
Common Usual Name: Looping Cardiac Event Recorder
Classification Name: Transmitters and Receivers, Electrocardiograph, Telephone (74DXH)

(3) Classification, Panel

Class II, 74DRX

(4) Predicate Devices:

1. Ralin Heart-Aide Event recorder
2. Braemar ER700 Event Recorder, K923930

(5) Description

The Paceart "Heart Access Plus"™ combines a "looping" cardiac event recorder and a voice diary. The "looping" feature permits the device to record a sample of the electrocardiogram both before and after the patient senses a symptom of a cardiac event and presses the "activator" button, unlike many other recorders which only record the ECG for a period after the sensing of the symptom. The voice diary permits a patient to record the circumstances which led to his making a recording.

The number and duration of events are programmable by the physician. The device can record up to 270 seconds of electrocardiogram. Each event can be programmed for 5 to 50 seconds of "pre-history" ECG (ECG before the activator button is pressed) and 5 to 95 seconds of "post-history" ECG (after the activator button is pressed). There can be one or two channels (two electrodes per channel, placed as desired) and up to six events: the total duration of all of the events for all of the channels is limited by the total record time of 270 seconds. The device will not permit

programming more events than can be stored, and once the memory is full no more electrocardiograms can be recorded. The voice diary permits recording up to 90 seconds of notes.

(6) Intended Use

The event recorder, called the "Heart Access Plus," is intended to be worn by the patient and to record a short period of electrocardiogram before and after the instant when the patient depresses a button upon sensing symptoms indicated to him by his physician. The unit also includes a voice diary by which the patient may record the symptoms at the time of recording.

(7a) Predicate Devices

The predicate devices for the Paceart Heart Access Plus are the Ralin Heart-Aide Event recorder and the Braemar ER700 Event Recorder, cleared under K923930 by TZ Medical, also known as the Heartaid Series TZ.

(7b) Testing

The Paceart Heart Access Plus has been compared in tests to one of the predicate device, and the two devices are equivalent. The Heart Access Plus has been tested according to AAMI EC38, Ambulatory Electrocardiographs, and meets the applicable requirements.

These tests all show that the Paceart Heart Access Plus is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

Dr. George Myers
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, New Jersey 07604

Re: K973141
Heart Access Plus Cardiac Event Recorder
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: August 18, 1997
Received: August 21, 1997

Dear Dr. Myers:

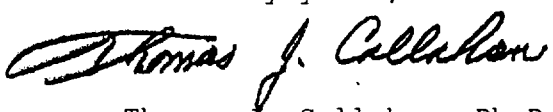
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/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

**510(k) Number (if known):** K973141

**Device Name:** Heart Access Plus Cardiac Event Recorder

**Indications for Use:**

The event recorder, called the "Heart Access Plus," is intended to be worn by the patient and to record a short period of electrocardiogram when the patient depresses a button upon sensing symptoms indicated to him by his physician. The unit is intended to be used in the patient's home, place of work, or when traveling. Recordings are then to be transmitted telephonically to a central receiver, where they are printed as received and then can be interpreted by a physician.

The unit also has a voice diary so that the patients can record notes of the circumstances when the event was recorded. The Heart Access Plus operates in the so-called "Looping" mode, in which it is always active, and in which it records an interval of one channel of cardiac activity before and an interval after the depression of the button; The durations of the intervals are programmable. The intended patient population is patients experiencing intermittent and unexpected cardiac events and arrhythmias.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Carlowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973141

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

(Optional Format 1-2-96)