

K972649

Reynolds Medical Ltd.  
CardioCall Event Recorder  
510(k) Submission

DEC - 4 1997

510(k) Summary

(1) Submitter Information

Name: Reynolds Medical Ltd.

Address: 1 Harforde Court  
John Tate Road  
Hertford SG13 7NW  
United Kingdom

Telephone Number: 44-1992-507700

Contact Person: Dr. George Myers (Official  
Correspondent)  
Medsys Inc.  
377 Rt 17 S  
Hasbrouck Heights, NJ 07604  
201-727-1703

Date Prepared: July 2, 1997, revised October 30, 1997

(2) Name of Device:

Trade Name: CardioCall Event Recorder  
Common Name: Cardiac Event Recorder  
Classification Name: Transmitters and Receivers,  
Electrocardiograph, Telephone (74DXH)

(3) Equivalent legally-marketed devices:

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

(4) Description

The CardioCall Event Recorder offers the user the choice of a looping cardiac event recorder (records the electrocardiogram both before and after the event) or a post-activation event recorder (records the electrocardiogram only after the event). Inserting the patient cable automatically changes the system from post-activation to looping. Embedded electrodes in the case are used for post-activation recording. The unit records one channel in looping mode and two channels in post-activation mode, and has a maximum recording time of 20 minutes. In looping, the unit records ten events with one minute before

and one minute after the event. Recordings can either be transmitted transtelephonically to a central station equipped with a standard transtelephonic receiver, or downloaded directly into a PC with the CardioConnect software, available as an option. The unit features a special battery conservation mode, to conserve battery power. While the device is compatible with a number of transtelephonic systems (the requirements are in the instruction book), all transtelephonic testing was done with the PaceArt receiving station.

#### (5) Intended Use

The event recorder, called the "CardioCall," 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 described to him by his physician. The CardioCall can either operate in the so-called "Looping" mode, in which it is always active, and in which it records a minute of one channel of cardiac activity before and a minute after the depression of the button; or in the "Post-Activation" mode, in which the device records two channels of cardiac activity for one minute after the depression of the record button. The PC computer program, called the "CardioConnect," is indicated when it is desired to transfer the memory of the event recorder into a computer by direct connection, instead of using transtelephonic means. The CardioCall recorder is indicated if it is desired to record the electrocardiogram at the time when a patient experiences intermittent or transient symptoms such as dizziness, palpitations, or shortness of breath, and the patient is capable of activating the recorder at these times.

#### (6) Technological characteristics

The device has the same technological characteristics as the predicate devices. All the devices have microcontroller control with solid-state storage for the electrocardiograms. They all use patient-operated buttons to activate the various functions.

The embedded electrodes have been tested for cytotoxicity. The specifications of the steel for the embedded electrodes will require the metal to meet the British equivalent of ASTM Standard F899-95, "Stainless Steel Billet, Bar, and Wire for Surgical Instruments".

(b) Performance data

(1) Non-clinical tests

Tests are included comparing the CardioCall to the predicate devices using an ECG simulator. The CardioCall and CardioConnect isolating cable have been tested to meet medical device safety standards EN60601-1 and UL2601-1 (these are equivalent to IEC 601-1). Tests included electromagnetic compatibility testing and were performed by approved testing agencies. The device is CE marked to certify compliance with the European EMC directive.

(2) Clinical tests

The CardioCall was compared to the predicate devices in a series of tests on human volunteers. The devices gave equivalent performance, and there were no adverse events. When transtelephonic transmission was required, the tests were all performed with the PaceArt transtelephonic system.

(3) Conclusions

The CardioCall is equivalent in safety and efficacy to the legally-marketed predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC -- 4 1997

Mr. George Myers  
Reynolds Medical Ltd.  
c/o Medsys Inc.  
377 Route 17 South  
Hasbrouck Heights, New Jersey 07604

Re: K972649  
CardioCall Cardiac Event Recorder  
Regulatory Class: II (two)  
Product Code: 74 DXH  
Dated: November 17, 1997  
Received: November 18, 1997

Dear Mr. 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.

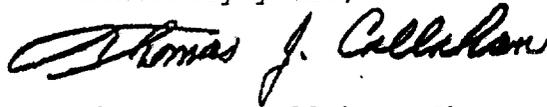
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. George Myers

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): K972649

Device Name: CardioCall Cardiac Event Recorder

**Indications for Use:**

[Revised 30 October 1997]

The event recorder, called the "CardioCall," 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 described to him by his physician. The CardioCall can either operate in the so-called "Looping" mode, in which it is always active, and in which it records a minute of one channel of cardiac activity before and a minute after the depression of the button; or in the "Post-Activation" mode, in which the device records two channels of cardiac activity for one minute after the depression of the record button. The PC computer program, called the "CardioConnect," is indicated when it is desired to transfer the memory of the event recorder into a computer by direct connection, instead of using transtelephonic means. The CardioCall recorder is indicated if it is desired to record the electrocardiogram at the time when a patient experiences intermittent or transient symptoms such as dizziness, palpitations, or shortness of breath, and the patient is capable of activating the recorder at these times.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*MS-prosten*

Prescription Use    
 (Per 21 CFR 810.109)

(Division Sign-Off)   
 Division of Cardiovascular, Respiratory,   
 and Neurological Devices

Over-the-Counter Use

510(k) Number \_\_\_\_\_

(Optional Format 1-2-96)