K991211

JUL -8 1999

Reynolds Medical Ltd.
510(k) Submission
EventStation ECG Trans-Telephonic Receiving System

510(k) Summary

(1) Submitter Information

Name: Reynolds Medical Ltd.

Address:

1-2 Hartforde Court
John Tate Court
Hertford, Herts SG137NW
ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: October 5, 1998

(2) Name of Device

Trade Name: EventStation ECG Trans-Telephonic Receiving System
Common Name: ECG Central Station Trans-telephonic system.
Classification name: Transmitters and Receivers, Electrocardiograph, Telephone, 74 DXH

(3) Equivalent legally-marketed devices.

1. Reynolds Cardio-Connect, K972649
2. Paceart Cardio-Voice, K952065.

(4) Description

The EventStation enables the physician to receive and review ECG recordings transmitted by the patient from a Reynolds CardioCall event recorder and other compatible event recorders.

The EventStation consists of a personal computer with voice modem, operating under Windows 98, and special software written by Reynolds Medical Ltd. The computer is assembled by Reynolds from standard components, and has been modified so that the operating system cannot be changed and unauthorized software cannot be loaded.

(5) Intended Use

The EventStation is intended to be used as a central receiving station for electrocardiograms that are recorded by Patient-Activated cardiac event recorders and then transmitted by telephone to a central station. It can operate in either an automatic "Unattended Mode" or a manual "Attended Mode." It has no ECG analysis capability, and is not intended to be used for this purpose.

(6) Performance Data

(a) Non-clinical tests

The EventStation software has been tested in accordance with EN60950, En 55022, and EN50082. EN 60950 is the standard required for non-patient contact equipment, and the other standards are for electromagnetic interference and immunity.

The EventStation software has undergone extensive validation testing.

(b) Clinical tests

An Equivalence test has been done on patients, to show that the EventStation is equivalent to a predicate device.

(c) Conclusions

The EventStation ECG Trans-Telephonic Receiving System is equivalent in safety and efficacy to the legally-marketed predicate devices.

Reynolds MEDICAL

Reynolds Medical Limited, 1 Harforde Court, John Tate Road, Hertford SG13 7NW England
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Reynolds Medical Ltd

Truthful and Accuracy Statement

EventStation Trans-Telephonic Receiving Station

The submitter believes that to the best of his knowledge that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Signed M F Maze

Title JOINT MANAGING DIRECTOR

Date 16 March 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 8 1999

Mr. George C. Myers
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K991211
EventStation ECG TransTelephonic Receiving System
Regulatory Class: II (two)
Product Code: DXH
Dated: April 9, 1999
Received: April 9, 1999

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 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" (21CFR 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

Page 1 of 1

510(k) Number (if known): K991211

Indications for Use Form

Device Name: EventStation Trans-Telephonic Receiving Station

Indications for Use:

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

for DBT 7/8/99

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)