

JUN 16 1998

Aerotel Ltd  
HeartView P 12/8 Event Recorder  
510(k) Submission

510(k) Summary

(1) Submitter Information

Name: Aerotel Ltd.

Address: 5 Hazoref Street  
58858 Holon  
Israel

Telephone Number: 972-3-559-6111

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

Date Prepared: Jan. 5, 1998

(2) Name of Device:

Trade Name: HeartView P 12/8 Event Recorder  
Common Name: Cardiac Event Recorder  
Classification Name: Transmitters and Receivers, Electrocardiograph, Telephone  
(74DXH)

(3) Equivalent legally-marketed devices:

1. Aerotel HeartView 12-lead event recorder, K950004
2. Meridian CardioBeeper, K965101
3. Aerotel H 1001, K931020

(4) Description

The HeartView P12/8 is a 12/8-lead Transtelephonic electrocardiographic recorder and transmitter which is intended to be used to record and transmit a patient's electrocardiogram (ECG) via the telephone to a diagnostic/emergency center. It is a modification to the Aerotel HeartView event recorder, K950004. For the original HeartView, the patient had 10 standard disposable electrodes attached to his chest by a physician, and the unit always recorded a 12-lead electrocardiogram. The HeartView P 12/8 can record either an eight lead or a twelve lead electrocardiogram, and has been designed so that the patient can attach the electrodes him/herself.

To record an 8-lead electrocardiogram, three standard disposable electrodes are attached to the patient's chest, and in addition the patient places the recorder in a specific place on his chest and makes recordings using "button" electrodes embedded in the case. To record a 12-lead electrocardiogram, the disposable electrodes are in the same locations but the patient makes three recordings using the embedded "button" electrodes, each with the recorder in a different location on the chest (also explained later). The system is designed so that the patient can attach the electrodes and place the embedded electrodes him/herself with the recorder in the proper locations. Clinical tests have been done which show that the electrocardiograms produced when the patient attaches the electrodes and manipulates the recorder are of the same quality as in the original HeartView, K950004, in which disposable electrodes are attached by the physician.

HeartView P12/8 has internal memory, which enables it to record and store the ECG of a cardiac event when the Record/Transmit button is pressed. The stored ECG can then be transmitted to the center by telephone at a later time. Transmitting the ECG does not erase it, so that an inadvertent or faulty transmission does not affect the recording.

The system is designed so that the patient can record an episode on the recorder and then transmit it in a simple, non-confusing way.

#### (5) Intended Use

The HeartView P12/8 is a 12/8-lead Transtelephonic electrocardiographic recorder and transmitter which is intended to be used to record and transmit a patient's electrocardiogram (ECG) via the telephone, to a diagnostic/emergency center. The HeartView P 12/8 can record either an eight lead or a twelve lead electrocardiogram, and has been designed so that the patient can attach the electrodes him/herself.

#### (b) Performance data

##### (1) Non-clinical tests

The HeartView P 12/8 has had to undergo safety and emissions tests. The HeartView P/12/8 has been tested for compliance with IEC 60601-1/1990 by Israel Testing Laboratories (ITL).

##### (2) Clinical tests

In a clinical test, electrocardiograms taken with the HeartView P 12/8 with the electrodes attached by the patient were compared to electrocardiograms taken with the predicate device, the HeartView 12-lead event recorder, with electrodes professionally attached. The electrodes were given to a cardiologist for comparison, who determined that the quality of the electrocardiograms from the two devices was equivalent.

##### (3) Conclusions

The HeartView P 12/8 is equivalent in safety and efficacy to the legally-marketed predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 16 1988

George H. Myers, Sc.D.  
Official Correspondent  
for Aerotel, Ltd.  
C/O Medsys, Inc.  
377 Route 17 South  
Hasbrouck Heights, NJ 07604

Re: K980144  
Trade Name: Aerotel HeartView P12/8 Cardiac Event Recorder  
Regulatory Class: II (two)  
Product Code: 74 DHX  
Dated: April 8, 1988  
Received: April 9, 1988

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.

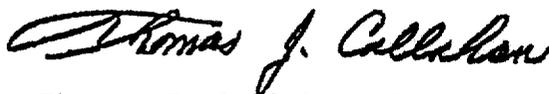
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 - George H. Myers, Sc.D.

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

Question 14. Indications for Use

The revised statement follows.

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510(k) Number (if known): K980144

Device Name: HeartView Cardiac Event Recorder

Indications for Use:

The HeartView P12/8 is a 12/8-lead Transtelephonic electrocardiographic recorder and transmitter which is intended to be used to record and transmit a patient's electrocardiogram (ECG) via the telephone to a diagnostic/emergency center. The HeartView P 12/8 can record either an eight lead or a twelve lead electrocardiogram, and has been designed so that the patient can attach the electrodes him/herself.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Debra L. Tull*

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

510(k) Number K980144

Prescription Use X  
Use \_\_\_\_\_  
(Per 21 CFR 810.109)

OR

Over-the-Counter

(Optional Format 1-2-96)