Aerotel Medical Systems (1998) Ltd.
Special 510(k)
Heart 2005 Cardiac Event Recorder

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements Regulation par. 807.92, effective March 14, 1995.

1. Submitter

Name: Aerotel Medical Systems (1998) Ltd
Address: 5 Hazoref St., Holon 58856, Israel
Telephone Number: 972-3-5596111
Contact person: Dr. George Myers, 210-787- 1703
Date prepared: March 7, 2000

2. Device

Proprietary name: Heart 2005
Common Name: Electrocardiograph Event Recorder and Telephonic Transmitter
Classification Name: Transmitters and Receivers, electrocardiograph, telephone

The Heart 2005 is a battery-powered ECG event recorder and transmitter that is capable of storing an electrocardiogram and transmitting it by means of a telephone to a central receiving station. It records a portion of the ECG both before and after a "Record" button is depressed.

3. Predicate Device

Modified Biolog (BIOPAT), K915624, manufactured by Aerotel for Micromedical Inc.

4. Description

The H2005 is a battery powered ECG Event Recorder and Transmitter which is intended to be used by the patient to record portions of a patient's electrocardiogram (ECG) and to send it to a receiving center such as Aerotel's Heartline 3000 (FDA # K930314) or equivalent. It records portions of the ECG both before and after the Record button is depressed.

5. Intended Use

K000175 p. 2/2

The **Heart 2005 is a** long-term portable electrocardiogram monitor intended to be used for long-term cardiac out-patient management. The unit records a period of electrocardiogram whenever the patient feels symptoms, as indicated to him by a physician, and presses a button on the unit. The electrocardiograms are then sent to the physician by telephone.

The unit is indicated whenever it is desired to have electrocardiograms of a symptomatic patient at the time of the symptoms. There are no known contraindications.

6. Comparison

The Heart 2005 is a modified version of the predicate device. It has basically the same electrical and mechanical characteristics, and the use of the two devices by the patient is equivalent It differs from the predicate device mainly in the construction methods.

7. Performance Data

(1) Non-clinical tests

The modifications were validated by repeating IEC 601-1 and IEC 601-1-2 tests (electrical safety and electromagnetic compatibility) and the electrical characteristic tests of standard EC38.

(2) Clinical Tests

No clinical tests were performed.

8. Conclusion

The conclusion drawn from these tests is that the Heart 2005 is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 7 2000

Aerotel Medical Systems (1998) Ltd.
C/O George H. Myers, Sc.D.
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K000775
Aerotel Medical Systems Heart 2005 Event Recorder and Transmitter
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: April 17, 2000
Received: April 18, 2000

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 control provisions of the Act. The general control 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K000775

Diagnostic Ultrasound Indications for Use Form

Device Name: Heart 2005

Indications for Use:

The **Heart 2005 is a** long-term portable electrocardiogram monitor intended to be used for long-term cardiac out-patient management. The unit records a period of electrocardiogram whenever the patient feels symptoms, as indicated to him by a physician, and presses a button on the unit. The electrocardiograms are then sent to the physician by telephone.

The unit is indicated whenever it is desired to have electrocardiograms of a symptomatic patient at the time of the symptoms. There are no known contraindications.

(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)

for Mark N Melkerson

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