K023418
A1/2

NOV 6 2002

Aerotel Medical Systems (1998) Ltd.
Special 510(k)
HeartOne 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 One
Common Name: Electrocardiograph Event Recorder and Telephonic Transmitter
Classification Name: Transmitters and Receivers, electrocardiograph, telephone

The HeartOne is a battery-powered ECG event recorder and transmitter that is capable of recording and storing an electrocardiogram and transmitting it by means of a telephone to a central receiving station.

3. Predicate Device

Aerotel H1001 Cardiac event recorder, K931020.

4. Description

The HeartOne is a battery powered post-event 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 the Aerotel Heartline Receiving Station K022073 or equivalent.

5. Intended Use

The HeartOne is intended to be used as a Patient/physician activated single lead ECG data recorder/transmitter, for recording ECGs and transmitting them over telephone lines to Aerotel's. Heartline Receiving Station

The unit is indicated whenever it is desired to have single-lead electrocardiograms of a patient. There are no known contraindications.

6. Comparison

The HeartOne 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, and in the fact that it can record four events, as contrasted to one event for the predicate device

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 HeartOne 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

NOV 6 2002

Medsys Inc.
c/o George H. Myers, Sc.D.
Official Correspondent
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K023418
Trade Name: HeartOne
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: October 7, 2002
Received: October 11, 2002

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

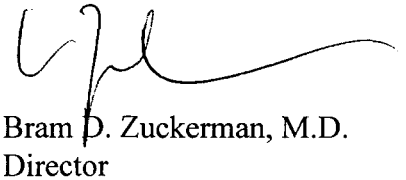
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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**510(k) Number (if known):** K023418

**Device Name: HeartOne**

**Indications for Use:**

The HeartOne is intended to be used as a Patient/physician activated single lead ECG data recorder/transmitter, for recording ECGs and transmitting them over telephone lines to Aerotel's Heartline Receiving Station

The unit is indicated whenever it is desired to have single-lead electrocardiograms of a patient. 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)**

Division of Cardiovascular & Respiratory Devices
510(k) Number K023418

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

**(Optional Format 1-2-96)**