



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 21 2003

Re: K032736
Device Name: Heart 2006
Dated: October 13, 2003
Received: October 16, 2003

Dear Dr. Myers:

We have reviewed the information dated October 13, 2003, regarding the 510(k) notification K032736 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

B Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K032736

Indications for Use Form

Device Name: Heart 2006

Indications for Use:

The **Heart 2006** is a long-term portable dual-channel 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
Use _____
(Per 21 CFR 810.109)

OR

Over-the-Counter

(Optional Format 1-2-96)