

K953762

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Aerotel Ltd.
 Heart 400 ECG Transmitter
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 Request for Additional Information
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 July 15, 1996
 revised 510(k) Summary

AEROTEL LTD.

510(k) Submission

Heart 400 ECG Transmitter (H400)

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 Ltd
 Address: 5 Hazoref St., Holon 58856, Israel
 Telephone Number: 972-3-5596111
 Contact person: Dr. George Myers, 201-438-2310
 Date prepared: July 13, 1995.

2. Device

Proprietary name: Heart 400
 Common Name: Electrocardiograph Telephonic Transmitter
 Classification Name: Transmitters and Receivers, electrocardiograph, telephone

The Heart 400 is a battery-powered ECG transmitter that is capable of transmitting a 3-channel ECG signal by means of a telephone to a central receiving station.

3. Predicate Device

Aerotel Heart 1001 ECG Transmitter, K931020

4. Description

The H400 is a battery powered 3-lead Transtelephonic ECG Transmitter which is intended to be used by the patient to transmit via the telephone a patient's electrocardiogram (ECG) to a receiving center such a Aerotel's Heartline 3000 (FDA # K930314) or equivalent.

The Heart 400 transmits each of leads I, II, III as selected by the patient. Patient connection is done by means of electrodes and a patient cable. The electrodes are attached by the physician.

To transmit the electrocardiogram, the telephone handset transmitter is placed over the device and the On/Off button of the H400 is released. At the receiving center, the ECG will be edited and recorded.

5. Intended Use

The H400 is a battery powered 3-lead Transtelephonic ECG Transmitter which is intended to be used by the patient to transmit via the telephone a patient's electrocardiogram (ECG) to a receiving center such a Aerotel's Heartline 3000 (FDA # K930314) or equivalent. The device is not intended to be used for long-term monitoring or when the patient is not capable of actuating the device or the telephone.

6. Comparison

The Heart 400 has basically the same physical characteristics as the predicate device, except that the Heart 400 does not have a memory. Thus, when the Heart 400 is used, the electrocardiogram is transmitted on the telephone at the same time it is taken, while with the Heart 1001 there can be a time lag. Apart from that, both use FM transmission, similar circuitry, and similar patient electrodes. This difference is not critical to the use of the device, because the Heart 400 is used when the electrocardiogram is to be transmitted immediately.

b. Performance Data

(1) Non-clinical tests

Non-clinical tests provided include bench tests of common mode rejection ratio, frequency response, sound level of the audio signal, temperature stress, electromagnetic immunity, and shock and vibration. There is no safety question, since the Heart 400 is battery operated.

(2) Clinical Tests

Electrocardiograms were taken from three volunteers using the Heart 400 and the Heart 1001, and transmitting the electrocardiograms over telephone lines. The quality of the electrocardiograms in every case is equivalent.

(3) Conclusion

The conclusion drawn from these tests is that the Heart 400 is equivalent in safety and efficacy to its predicate device.