Aerotel Medical Systems (1998) Ltd.
510(k) Submission
BP-Tel Trans-Telephonic Blood Pressure Measurement System

510(k) Summary

(1) Submitter Information

Name: Aerotel Medical Systems (1998) Ltd.

Address:

5 Hazoref Street
58858 Holon
Israel

Telephone Number: 972-3-559-6111

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: October 5, 1998

(2) Name of Device

Trade Name: BP-Tel Trans-telephonic blood pressure measurement system
Common Name: Home blood-pressure measurement device and trans-telephonic transmission system.
Classification name: Monitor, Blood-Pressure, Amplifier and Associated Electronics, 74 KGJ.

(3) Equivalent legally-marketed devices.

1. UA 767 Home Blood Pressure System, K871720
2. Aerotel Central System for Event Recorders, K930314
3. Aerotel ECG HeartView Cardiac Event recorder, K950004

(4) Description

The system includes a home blood-pressure measuring device that makes use of the oscillometric system, a means for sending the measurements over the telephone lines to a central station, and a computer program at the central station for receiving the measurements, storing them in a data base, and preparing reports.

(5) Intended Use

The Aerotel BP-Tel Trans-Telephonic Monitoring system is intended to be used by patients to measure their blood pressure at home and transmit it to a central station by telephone. The system includes both the patient unit and a central computer program (to be used in a Personal Computer) which receives the blood pressure data, stores it in a patient's record, and prepares reports and charts showing the history of the systolic, diastolic pressures and the heart rate. It is not intended to be used by patients with defibrillators.

(6) Performance Data

(a) Non-clinical tests

The BP-Tel system has been tested by an outside testing laboratory for compliance with EN 60601-1, and satisfactorily passed all tests.

The MPM software has undergone extensive validation testing.

(b) Clinical tests

The actual blood-pressure device is a cleared device purchased for this system. The entire system has been tested in a clinical test with volunteer subjects.

(c) Conclusions

The BP-Tel Blood-Pressure trans-telephonic monitoring system is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

Mr. George H. Myers
Official Correspondent
MEDSYS, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K983717
Aerotel BP-Tel
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: August 10, 1999
Received: August 11, 1999

Dear Mr. Myers:

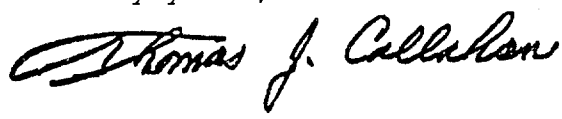
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 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 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983717

Indications for Use Form

Device Name: BP-Tel Trans-Telephonic Blood Pressure Measurement System

Indications for Use:

The Aerotel Medical Systems (1998) Ltd BP-Tel Trans-Telephonic Monitoring system is intended to be used by patients to measure their blood pressure at home and transmit it to a central station by telephone. The system includes both the patient unit and a central computer program (to be used in a Personal Computer) which receives the blood pressure data, stores it in a patient's record, and prepares reports and charts showing the history of the systolic, diastolic pressures and the heart rate. The BP-Tel is not intended for patients with defibrillators.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan B Campbell

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983717

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

(Optional Format 1-2-96)