K041854

p1/2

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: June 3, 2004

(2) Name of Device

Trade Name: MPM System
Common Name: Device for transmitting measurement parameters from the home and receiving them at a central station with Internet Access.
Classification name: Telephone electrocardiograph transmitter and receiver.

(3) Equivalent legally-marketed devices.

1. Cybernet Medical Medstar, K020534
2. Aerotel BPTEL/MPM, K983717
3. Aerotel TeleCliniQ, K021447
4. Aerotel MPMP-Net, K030825

(4) Description

The system comprises a modem-like device that connects to various cleared measurement devices and a ıtral station program that keeps the records of the patients, prepares reports, and makes the reports available ...ı the internet.

(5) Intended Use

The Aerotel MPM SYSTEM is intended to be used with home patient monitoring devices (blood pressure, digital scale, blood glucose level, respiratory peak flow, pulse oximetry) to send the measured data to a central station via modem by telephone, where reports can be generated for the physician and reports can be received over the Internet by physicians and patients.

(6) Performance Data

(a) Non-clinical tests

The system has been tested with all of the compatible measuring units and has satisfactorily passed the tests. The software has been extensively validated.

(b) Clinical tests

Clinical tests are not necessary because the device does not use new technology/

(c) Conclusions

The MPM 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

OCT 6 - 2004

Aerotel Medical Systems, Ltd.
c/o George H. Myers, Sc.D.
Medsys, Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K041854
Trade Name: MPM System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 7, 2004
Received: July 8, 2004

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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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): K041854

Indications for Use Form

Device Name: MPM System

Indications for Use:

The Aerotel MPM SYSTEM is indicated when patients use with home patient monitoring devices (blood pressure, digital scale, blood glucose level, respiratory peak flow, pulse oximetry) and wish to send the measured data to a central station via modem by telephone, where reports can be generated for the physician and reports can be received over the Internet by physicians and patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K041854