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K021447
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Aerotel Medical Systems (1998) Ltd.
Special 510(k) Submission
Tele-CliniQ
April 26, 2002

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: April 16, 2002

(2) Name of Device

Trade Name: Tele-CliniQ
Common Name: Clinical Data Transmission System for Blood Pressure
Classification name: Monitor, Blood-Pressure, Amplifier and Associated Electronics, 74 KGJ.

(3) Equivalent legally-marketed devices.

Aerotel BP-Tel, K 983717

(4) Description

The system includes a home blood-pressure measuring device that makes use of the oscillometric system (purchased separately), 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 Tele-CliniQ is intended to be used by patients to transmit blood pressure measurements taken at home 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 Tele-CliniQ has been tested by an outside testing laboratory for compliance with EN 60950 electrical safety, and for electromagnetic compatibility, and has satisfactorily passed all tests.

The MPM software has undergone extensive validation testing.

The UA 767 PC (blood pressure measurement device) has been cleared by the FDA.

The entire system has been validated.

(b) Clinical tests

Not required.

(c) Conclusions

The Tele-CliniQ 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

MAY 22 2002

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

Re: K021447
Trade Name: Tele-CliniQ Clinical Data Transmission System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 2, 2002
Received: May 6, 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K021447

Indications for Use Form

Device Name: Tele-ClinQ Clinical Data Transmission System

Indications for Use:

The Aerotel Medical Systems (1998) Ltd Tele-CliniQ Data Transmission 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 (purchased separaetly) 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. The Tele-CliniQ 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)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021447

Prescription Use X