510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Sponsor:

Recom Managed Systems, Inc.
4705 Laurel Canyon Blvd. #203
Valley Village, CA 91607
Phone (818) 432-4560
Facsimile (818) 432-4566

Contact Person: William R. Matthews, Consultant

Date Prepared: September 15, 2003

2. Device Name: Recom Model 100, battery-operated Ambulatory, Digital, Wireless ECG Monitor System

Trade or Proprietary Name:
Recom Model 100, battery-operated, Ambulatory, Digital, Wireless ECG Monitor System

Common or Usual Name:
Ambulatory Electrocardiograph Recorder

Classification Name:

- 21 CFR 870.2800 - Electrocardiograph, Ambulatory (without analysis)
- 21 CFR 870.2910 - Radiofrequency Physiological Signal Transmitter and Receiver

3. Predicate Devices:

The Recom Model 100, battery-operated, Ambulatory, Digital, Wireless ECG Monitor is equivalent to:

- CardioNet Ambulatory ECG Monitor, CardioNet, Inc., K003707
- Mortara Ambulatory X-12 Telemetry Module, Mortara Instruments, Inc. K974149

4. Intended Use:

The Recom Model 100 battery-operated Ambulatory, Digital Wireless, ECG Monitor System is a true 12 lead ambulatory ECG monitor system capable of recording up to 48 hours of ECG data for the purpose of cardiac monitoring and diagnosis by a medical professional where ambulatory (Holter) monitoring is prescribed

by a physician. The system includes recording of ECG data from each of the 12 leads, RF transmission of the recorded data to a PDA and storage.

The stored ECG data is then transferred from the PDA to another device, the Phillips Medical TraceMaster ECG Analysis System for ECG analysis. The Recom Model 100 battery-operated, Ambulatory, Digital, Wireless ECG Monitor System is not intended to sound any physiological alarms.

The Recom Model 100 battery-operated, Ambulatory, Digital Wireless ECG Monitor System is only to be used by or on the order of a physician.

5. Device Description:

The device is a true 12 lead, battery-operated, ambulatory (Holter), digital, wireless, ECG monitor. The device acquires an ECG signal from 10 patient surface contact electrodes. Each electrode is connected to a cable that is connected to the Recom patient worn monitor/transmitter. The ECG signal is transmitted from the electrodes via the cable to a battery-operated ECG monitor unit worn by the patient where the signal is processed utilizing the company's signal processing technology and transmitted via radio frequency (Bluetooth) to a hand held Personal Digital Assistant (PDA) capable of recording up to 48 hours of ECG data.

The PDA converts the signal stream into a specific data format where it is stored on a compact flash card for transmission to and analysis by another device, the Phillips Medical TraceMaster ECG Analysis System K032103.

Monitoring data is not real time but is recorded and stored for further analysis by the Phillips System. The ECG data produced consists of Leads I, II, III, aVR, aVL, aVF and V1 through V6. The Recom Model 100 Ambulatory, Digital, Wireless monitor is not intended to alarm.

The fundamental technology of the Recom battery-operated, Ambulatory, Digital ECG Monitor System is the same as that of the predicate devices. The Recom Ambulatory, Digital, Wireless ECG Monitor System relies on the company's signal processing technology to minimize noise in the ECG signal created by the ambulatory nature of the signal source.

6. Basis for Substantial Equivalence:

The Recom battery-operated, Ambulatory, Digital, Wireless ECG Monitor, the CardioNet Ambulatory ECG Monitor and the Mortara X-12 Telemetry Module are all intended to collect Ambulatory ECG data in a digital format by a wireless means for analysis.

Like the predicate devices, the Recom Model 100 Ambulatory, Digital, Wireless ECG Monitor System records ECG data in an ambulatory setting and transmits the data by radiofrequency means for analysis at another location.

An examination of the differences between the Recom Model 100 battery-operated, Ambulatory, Digital, Wireless ECG Monitor System does not raise new questions of safety or effectiveness.

Prior to marketing, the proposed Recom Ambulatory, Digital Wireless, ECG Monitor System will comply with all pertinent recognized industry standards for Ambulatory, Digital, Wireless Electrocardiograph devices. These include ANSI/AAMI EC-38, ANSI/AAMI EC-11, IEC 60601-1-2, IEC 60601-1-2-27 and UL 2601-1. The communications of the monitor will meet the applicable requirements of FCC Part 15.

Performance testing demonstrates that ECG tracings can be accurately and reliably produced by the Phillips Medical Systems TraceMaster ECG Management System from the file stored on the storage memory card of the PDA. The technical differences between the proposed Recom device and the predicate devices do not raise any new concerns of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2004

Recom Managed Systems, Inc.
c/o Mr. William R. Matthews
Regulatory Affairs Consultant
4705 Laurel Canyon Blvd. #203
Valley Village, CA 91607

Re: K032882
Trade Name: Recom Model 100, Battery-Operated, Ambulatory, Digital Wireless ECG Monitor System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: November 5, 2003
Received: November 5, 2003

Dear Mr. Matthews:

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) 594-4646. 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

Indications for Use Statement

510(k) Number (if known): K032882

Device Name: Recom Model 100, battery-operated, Ambulatory, Digital Wireless ECG Monitor System

Indications for Use:

The Recom Model 100 battery-operated Ambulatory, Digital Wireless ECG Monitor System is a true 12 lead ambulatory ECG monitor system capable of recording up to 48 hours of ECG data for the purpose of cardiac monitoring and diagnosis by a medical professional where ambulatory (Holter) monitoring is prescribed by a physician. The system includes recording of ECG data from each of the 12 leads, RF transmission of the recorded data to a PDA and storage.

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The Recom Model 100 battery-operated, Ambulatory, Digital Wireless ECG Monitor System is only to be used by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond
Division of Cardiovascular & Respiratory Devices
510(k) Number K032882

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)