K063339

510(k) Summary of Safety and Effectiveness

JUN 2 9 2006

Submitter Information:

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USA Contact:

B. Harlow & Associates, LLC
803 NE Juanita Drive
Kirkland, WA 98034
USA

Phone: 425 891-7347
FAX: 425 823-4469

Device Name:

Trade Name: Medick MHM200 Personal Heart Monitor
Common Name: Event Recorder
Classification Name: Electrocardiograph, Ambulatory, with Analysis Algorithm

Predicate Device:

The Medick MHM200 Personal Heart Monitor is substantially equivalent to the C.Net 2100 Single Channel ECG Ambulatory Monitor cleared for market by the United States Food and Drug Administration under 510(k) number K010396.

Device Description:

The Medick MHM200 is an ECG testing device that monitors heart on a beat by beat basis to detect any irregularities. It does this over a period of up to 8 hours and reports a person's heart rhythm. It is small, light weight, portable, single channel ECG ambulatory monitor equipped with an LCD that is used to set-up the monitor and display cardiac information. The monitor is powered by two (2) standard AAA alkaline batteries. The MHM200 can communicate with a computer over a standard USB connection to store and print a person's cardiac information. For safety reasons, the MHM200 uses proprietary patient and USB cables. The cables share a common input connector. The patient cable must be removed before the monitor can be connected to a computer through the USB cable.

Indications for use:

The MHM200 Monitor is intended for in-context monitoring of adult patients where symptoms occur infrequently or where resting ECG monitoring is unlikely to capture symptomatic or asymptomatic abnormal rhythm events.

Its use includes assessing symptoms (including palpitations, dizzy spells, paroxysmal light-headedness, and pounding of the heart) that may relate to disturbances of the heart.

Where it is clinically appropriate, the MHM200 Monitor can assist in ongoing monitoring of the frequency of abnormal rhythm events in patients receiving anti-arrhythmic medication or rehabilitation therapy.

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Technology Characteristics:
Technology characteristics of the Medick MHM200 are substantially equivalent to the C.Net 2100. Both products were developed by Cardionetics Ltd. The ECG channel and arrhythmia analysis algorithm are the same. New software has been added to the MHM200 to drive the LCD display and the housing has been changed to accommodate the display. New directions for use were developed to describe the display and ensure that the operator can use the MHM200 safely and for the purpose for which it is intended.

Summary of Performance Testing:

Item	Title	Number
1	Safety: IEC/EN 60601-1 Medical Electrical Equipment – Part 1 General Requirements for Safety	IEC/EN 60601-1
2	Safety: IEC/EN 60601-1 Medical Electrical Equipment – Part 1 General Requirements for Safety, 1988:Amendment 1, 1991-11, Amendment 2, 1995	IEC/EN 60601-1 Amendment 1 & Amendment 2
3	EMC: EN 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electrometric Compatibility – Requirements and Tests	IEC/EN 60601-1-2
4	Patient Cables: 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables	21 CFR 898
5	Disposable ECG electrodes	AAMI/ANSI EC 12:2000
6	ECG: AAMI/ANSI EC38:1998 Ambulatory Electrocardiographs	AAMI/ANSI EC38:1998
7	Cardiac Rhythm: AAMI/ANSI EC57-98 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment measurement Algorithms	AAMI/ANSI EC57-98

The Medick MHM200 has been tested and conforms to the appropriate sections of the above noted standards.

Conclusion:
The Medick MHM200 Personal Heart Monitor is as safe and effective as the predicate devices when used according to the instructions in the directions for use supplied with the monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Medick Healthcare Ltd.
c/o James W. Sandberg, P.E.
B. Harlow & Associates
8303 N.E. Juanita Drive LLC
Kirkland, WA 98034

Re: K063339
Trade Name: Medick MHM 200 Personal Heart Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: MLO
Dated: June 26, 2007
Received: June 27, 2007

Dear Mr. Sandberg:

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 240-276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lichner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K063339

Device Name: Medick MHM200 Personal Heart Monitor

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Prescription Use ____ X _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Krochmal
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063339