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"510(k) Summary"
As Required By 21 CFR Section 807.92(c)

Applicant's Name: **Universal Medical Incorporated**
275 Phillips Blvd, Ewing, New Jersey 08618
Phone (609) 671-1790 Fax (609) 671-1765

Establishment Registration Number: 2248680

Contact Person: Steven Adamsky

Date: 09-19-2007

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Proprietary Name: ***Heartrak Smart AF (K071130)***

Classification Name: Telephone Electrocardiograph Transmitter and Receiver 21 CFR 870.2920.

Predicate Devices: ***Heartrak Smart AT (K033451)***

Device Description:
Heartrak Smart AF is a hand-held, portable, externally applied transtelephonic cardiac event recorder device, which is intended for transtelephonic use.

Intended Use:
Heartrak Smart AF is a hand-held, portable, externally applied transtelephonic cardiac event recorder, which is intended for transtelephonic use.

Indication for Use:
Heartrak Smart AF is a hand-held, portable, externally applied transtelephonic cardiac event recorder device, which is intended for transtelephonic use. Patient calls a receiving center at the hospital or physicians office from the patient's home to play back the recording. Heartrak Smart AF converts ECG signals into audio tones which are transmitted over the telephone lines. Heartrak Smart AF does not deliver any energy, administer any drugs, or controls a patient's life. Heartrak Smart AF is not a diagnostic tool and performs no diagnostic functions.

Technological Characteristics:
All of the technological characteristics are identical to the predicate device, including design, material, and energy source. A module to better detect Atrial Fibrillation was added to the Heartrak Smart AT (predicate device) firmware to develop the Heartrak Smart AF (subject device). The Heartrak Smart AT device and Heartrak Smart AF device are otherwise identical in materials and technology.

Substantial Equivalence:

The Heartrak Smart AF is substantially equivalent to the predicate device, Heartrak Smart AT. The safety and effectiveness of this device is substantially equivalent to the predicate device. There are no known contradictions for use of this type of device. All of the features in this device present a non-significant risk to the user. The Substantial Equivalence Table is presented in the submission, Section 12 Substantial Equivalence Discussion.

A module to better detect Atrial Fibrillation was added to the Heartrak Smart AT (predicate device) firmware to develop the Heartrak Smart AF (subject device). The Heartrak Smart AT device and Heartrak Smart AF device are otherwise identical in materials and technology.

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Conclusions Based on Tests Submitted:

All testing performed on the Heartrak Smart AF device was derived from the risk assessment that evaluated the effects of the addition of the atrial fibrillation detection module to the existing Heartrak Smart AT arrhythmia detection firmware. Heartrak Smart AF testing included environmental and software validation testing and device testing.

The atrial fibrillation detection module was tested, using available annotated MIT-BIH AFIB database and MIT-BIH Arrhythmia database (Series 100 and Series 200), which are annotated ECG databases, and the MIT Wave Form Data Base (WFDB) software to derive performance statistics for Heart Smart AF. Testing was performed in compliance with standard evaluation protocols. These protocols have been adopted as parts of the ANSI/AAMI EC38:1998; IEC 60601-1; IEC 61000-4, and ANSI/AAMI EC57:1998/R2003 recommendations for testing cardiac rhythm and reporting the results of those tests. They include earlier evaluation protocols developed for an AAMI Recommended Practice, *Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms* (AAMI ECAR, 1987).

The subject device, Heartrak Smart AF, has indications for use the same as the predicate device, Heartrak Smart AT. The testing included in our submission in Section 18 Performance Testing – Live Patient/Field Test and Bench Test demonstrates that there are no differences in the technological characteristics of the subject device and the predicate device; therefore there are no new issues of safety or effectiveness. Heartrak Smart AF is substantially equivalent to the predicate device, Heartrak Smart AT.

Promotional Material:

Instructional manual, labeling.

Address for Manufacturing Site:

Heartrak Smart AF will be manufactured by Universal Medical, Inc. at its offices at 275 Phillips Boulevard, Ewing, New Jersey 08618.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Universal Medical, Inc.
c/o Mr. Steven Adamsky
Executive Vice President
275 Philips Blvd.
Ewing, NJ 08618

Re: K071130
Heartrak Smart AF
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: April 24, 2008
Received: April 25, 2008

Dear Mr. Adamsky:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Enclosure

UNIVERSAL MEDICAL INCORPORATED

275 Phillips Blvd, Ewing, NJ 08618 (800) 606-5511 Fax (800) 889-5383

Indications for Use

510(k) Number (if known): **K071130**

Device Name: **Heartrak Smart AF**

Indications for Use:

Heartrak Smart AF is a hand-held, portable, externally applied, cardiac event recorder that is intended for transtelephonic use. Patient calls a receiving center at the hospital or physician's office from the patient's home to play back the recording. Heartrak Smart AF converts electrocardiogram (ECG) signals into audio tones which are transmitted over the telephone lines.

Heartrak Smart AF does not deliver any energy, administer any drugs, or control a patient's life. Heartrak Smart AF is not a diagnostic tool and performs no diagnostic functions.

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

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071130