5. 510(k) Summary or 510(k) Statement

K083535

DEC 15 2008

Date: October 30, 2008

Submitter/Owner: Universal Medical, Inc.

Official Contact Person Authorized by the Submitter:

Mark Job, Third-Party Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313
Telephone: 763 682 4139
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Email: mark@markjob.com

Device Type: cardiac event recorder; electrocardiograph transmitter

Device Class: II

Regulation Number 870.2920

Review Panel: Cardiovascular

Basis for the Submission: new design incorporating wireless technology.

Predicate Devices

Predicate devices for which Universal Medical, Inc. is claiming equivalence:

510(k) Number	Trade or Model Name	Manufacturer	Classification Name	Product Code
K071130	Heartrak Smart AF	Universal Medical, Inc.	transmitters and receivers, electrocardiograph, telephone 870.2920	DXH
K060911	Cg-6108 Arrhythmia ECG Event Recorder	Card Guard Scientific Survival, Ltd.	transmitters and receivers, electrocardiograph, telephone 870.2920	DXH

Device Description

Heartrak Smart ECAT is a cardiac event recorder that is used to continuously scan and capture ECG signals. Patients can use Heartrak Smart ECAT to capture ECG data both before and after they experience a cardiac symptom. Heartrak Smart ECAT can capture and automatically record asymptomatic, infrequent, or illusive arrhythmia events such as Bradycardia, Tachycardia, and Atrial Fibrillation.

Heartrak Smart ECAT can store up to 30 days of ECG data in its memory. The physician can use a compatible wireless device to set event recording times and autotriggering parameters and then upload them to a patient's monitor.

Using wireless technology, Heartrak Smart ECAT, when placed within range (less than 10 meters) of an RF compatible receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

The physician is to instruct the patient on the proper use and care of the Heartrak Smart ECAT monitor. Patients should be told to contact their physician if they have any further questions.

Intended Use

Heartrak ECAT is a hand-held, portable, externally applied, cardiac event recorder; electrocardiograph transmitter.

tel 800.606.5511 • fax 800.889.5415 • 275 Phillips Blvd., Ewing, NJ 08618 • www.mednethealth.net

Indications for Use

Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using wireless technology, Heartrak Smart ECAT, when placed within range of an RF compatible receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

Heartrak Smart ECAT does not deliver any energy, administer any drugs, make any diagnosis, or control a patient's life. Heartrak Smart ECAT is for prescription use only.

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Technological Characteristics (Substantial Equivalency Table)

The table below shows that the technological characteristics of Heartrak Smart ECAT are substantially equivalent to the predicate devices:
Heartrak Smart AF (K071130) manufactured by Universal Medical, Inc. in functionality
CG-6108 Arrhythmia ECG Event Recorder (K060911) manufactured by Card Guard Scientific Survival, Ltd. in wireless communication

Table 1 Substantial Equivalency Table

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Intended use	Heartrak Smart ECAT is a hand-held, portable, externally applied, cardiac event recorder; electrocardiograph transmitter.	Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.	Heartrak Smart AF is a hand-held, portable, externally applied, cardiac event recorder that is intended for transtelephonic use.
Indications for use	Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using	The CG-6108 system is an Arrhythmia ECG Event Recorder designed for self-testing by patients at home and for analysis by medical professionals at a remote monitoring center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.	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 physicians office from the patient's home to play back the recording. Heartrak Smart AF converts electrocardiogram (ECG) signals into audio tones which

	Heartrak Smart ECAT Universal Medical, Inc.	CG-6108 Arrhythmia ECG Event Recorder (K060911) Card Guard Scientific Survival, Ltd.	Heartrak Smart AF (K071130) Universal Medical, Inc.
	wireless technology, Heartrak Smart ECAT, when placed within range of a compatible RF receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center. Heartrak Smart ECAT does not deliver any energy, administer any drugs, make any diagnosis, or control a patient's life. Heartrak Smart ECAT is for prescription use only.	The chest-worn unit includes 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal. The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected, it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post-processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds, which starts recording based on specific rhythms and arrhythmias detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by	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.

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	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
		the CG Monitoring Center. The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.	
Monitor Features			
Patient Cable	3-lead patient cable	3-lead patient cable	2-lead patient cable
Lead off Detection	Yes	Unknown	No
Channel Recording	3	3	1
Monitoring Mode	Continuous	Continuous	Loop
Data Transmission	Radio Frequency (RF)	Radio Frequency (RF)	Transtelephonic FM
Recording Button	Yes	Yes	Yes
Playback Button	No (When User puts monitor within range of a compatible RF receiver, the monitor automatically uploads recorded ECG data to the receiver.)	No (When User puts monitor within range of a compatible RF receiver, the monitor automatically uploads recorded ECG data to the receiver.)	Yes
Reset Button	No	No	Yes
Unintentional Erase Data Protection	Yes	Unknown	Yes

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	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Power Loss Data Protection	Yes	Unknown	Yes
Available Programming/Configuration Options			
Programmable pre/post recording times	Multiple	Yes	Multiple (Total memory 10 minutes)
Number of events	Multiple	Multiple	Multiple
Patient Manual Activation	Yes	Yes	Yes
Silent Recording	Yes	Unknown	Yes
Auto-Triggering	Yes	Yes	Yes
Bradycardia	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)
Tachycardia	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)
Atrial Fibrillation	Yes	Yes	Yes
Auto-Trigger On/OFF capability	Yes	Unknown	Yes
Monitor Physical Characteristics			
Dimensions	7.4 cm length x 5.3 cm wide x 1.8 cm thick Weight with batteries 90 gm	75 x 58 x 23 mm (max.) Net weight 54 gm	7.4 cm length x 5.3 cm wide x 1.8 cm thick Weight with batteries 90 gm

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	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Monitor Technical Characteristics			
Transmission Mode (Bluetooth 2.0 SPP Profile)	Yes	Yes	N/A
RF transmission range	10 meters open space	10 meters open space	N/A
Bandwidth	0.05 – 30 Hz	60 Hz	0.05 – 30 Hz
Recording Period	3 channel, 30 days	1-lead, up to 24 hours	9 minutes
Monitor Electrical Characteristics			
Input Impedance	With supplied leads @ 5Hz 2 MOhm	20 MOhm	With supplied leads @ 5Hz 2 MOhm
Differential Input @ AC 15 Hz	± 3 mV	+5 mVp-p	± 3 mV
Differential Input Range	DC ± 250 mV	DC ± 165 mV	DC ± 250 mV
Common Mode Ratio (CMR)	60 dB	60 dB	60 dB
Common Mode Ratio Range (CMRR) AC + DC	± 0.5V	Unknown	± 0.5V
Monitor Battery			
Battery type	Internal Li-Ion rechargeable battery 3.6V	3.6V AA	AA 1.5V
Battery life	3 days	10 days	14 days (1 event recorded and transmitted each day
Monitor Environmental Characteristics			
Operating temperature	+10 to +40 degrees C	+10 to +40 degrees C	+10 to +40 degrees C

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Transport and storage temperature	-20 to 65 degrees C	-20 to 65 degrees C	-20 to 65 degrees C
Relative humidity	10% to 90%	30% to 85%	10% to 90%

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

Universal Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K083535
Trade/Device Name: Heartrak Smart ECAT
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: November 26, 2008
Received: November 28, 2008

Dear Mr. Job:

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 Biometrics' (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,

Donna R. Zuckerman

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

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K083535

Device Name: Heartrak Smart ECAT

Indications for Use

Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using wireless technology, Heartrak Smart ECAT, when placed within range of a compatible RF receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

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

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

510(k) Number K083535