

510(k) Summary**Date: 02/04/2013****Submitter Name and Address**

Braemar Manufacturing LLC
750 B St. Suite 1400
San Diego, CA 92101

Contact Person

Kent Saylor
Tel # 619-243-7560

OCT 16 2013

Name of Device

Trade/Proprietary Name: Model CK100 - CardioKey Holter Recorder
Common/Usual Name: Medical Magnetic Tape Recorder
Classification Name: CFR §870.2800 Product Code: MWJ Medical
Magnetic Tape Recorder
Class: Class II

Predicate Device

The predicate device is as follows:

Braemar Model DL900 Series Holter Recorder manufactured by Braemar, Inc. cleared by FDA under 510(k) number K071733; 870.2800 Product code MWJ 'Medical Magnetic Tape Recorder' on July 24, 2007

Device Description

The CardioKey Holter Recorder, Model CK100, is an ambulatory ECG recorder which is comprised of three (3) main components: 1) a patient-worn Sensor, 2) a Lead wire and 3) a host application.

The Sensor is a USB dongle that acquires ECG data and stores the data in non-volatile memory. The Sensor is worn for up to 14 days and operates on one coin cell battery for the duration of the recording period. This Sensor can plug directly into a host computer's USB port for data transfer.

The female end of the lead wire cable assembly plugs onto the Sensor. The lead wire cabling on the other end of the assembly is connected to the User via two electrodes

The host application extracts user data from the Sensor and translates it to processing by a 510(k) cleared third party analysis software.

Indications for Use

The indications for use for the subject device are as follows:

The CardioKey Holter Recorder is intended for patients requiring ambulatory (Holter) monitoring. Such monitoring is most frequently used for the indications below:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
3. Evaluation of patients for ST segment changes
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g. after M.I. or cardiac surgery)
5. Clinical and epidemiological research studies
6. Reporting of time and frequency domain heart rate variability
7. Reporting of QT interval

Technological comparison to predicate device

The primary technological differences between the subject device and the predicate device (K071733) are that the subject device uses a common coin cell battery while predicate device uses a AAA alkaline battery and the recording time is minimum 14 days for the subject device while predicate device records up to 7 days only. The subject device also has higher memory capacity. The subject device records only one channel of data while predicate device can record 2 or 3 channels.

Summary of Performance Testing

The CardioKey Holter Recorder Model CK100 meets the requirements of following performance standards,

- ANSI/AAMI EC 38:2007 – Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- IEC60601-1:1988+A1:1991+A2:1995 - Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC60601-1-2:2007 - Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Substantial Equivalence Conclusion

CardioKey Holter Recorder, Model CK100 is safe, effective, and substantially equivalent to the predicate device as supported by the descriptive information and the performance testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

Braemar Manufacturing, LLC
c/o Mr. Kent Sayler
VP of Regulatory Affairs and Quality Assurance
750 B Street, Suite 1400
San Diego, CA 92101

Re: K130294
Trade/Device Name: Model CK100 – Braemar CardioKey Holter Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: September 13, 2013
Received: September 16, 2013

Dear Mr. Sayler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Faris -S

for 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 (if known): K130294

Device Name: Model CK100 - Braemar CardioKey Holter Recorder

Indications for Use:

The CK100 CardioKey Holter Recorder is intended for patients requiring ambulatory (Holter) Monitoring. The following is a listing of the most frequent indications for use:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.
6. Reporting of time and frequency domain heart rate variability.
7. Reporting of QT Interval.

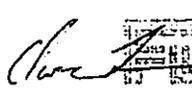
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Digitally signed by
Owen P. Paris -S
Date: 2013.10.16
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