K063042

Special 510(k) Notification	getemed
CardioMem® CM 3000-12BT	Project ID: 0608H1
510(k) - Summary	Section 16-0001-Rev A

MAY 30 2007

510(k) - Summary

Name and address of the manufacturer and sponsor of the 510(k) submission:	getemed AG Oderstr. 59 14513 Teltow Germany Tel.: +49 3328 – 3942-0 Fax: +49 3328 – 3942-99
Official contact person for all correspondence:	Dr. Bert Schadow Regulatory Affairs Manager E-mail: schadow@getemed.de
Manufacturing Facility:	getemed Medizin- und Informationstechnik AG Oderstr. 59 14513 Teltow Germany
Date of Preparation:	2006-09-22
Device Name / Trade Name:	CardioMem® CM 3000-12BT Holter recorder
Generic name of the device:	Electrocardiograph, ambulatory (without Analysis)
Classification of new device:	Class II
Classification Panel:	Cardiovascular
Product Code and	MWJ
CFR Regulation Numer:	21 CFR 870.2800
Predicate Devices Name and 510(k) Numbers:	CardioMem® CM 3000-12 Holter recorder K051686 CG-7000DX-BT ECG Recorder/Transmitter K052556

Description of Device:

The CM 3000-12BT is a Holter recorder designed to be used in conjunction with the evaluation software CardioDay® (K051471). This recorder is not capable of any diagnosis nor can it provide any interpretation of the data. The CM 3000-12BT acquires, digitizes and stores data to be analyzed by CardioDay®. The CM 3000-12BT utilizes a 10-lead electrode hookup and placement to provide CardioDay® with 12 channels of full disclosure for Holter analysis. The cardiac data provided by CardioDay® is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns. The CM 3000-12BT Holter recorder stores 12 ECG channels continuously for up to 48-hours including the detection of pacemaker pulses. A keypad is available to set up system configuration, to enter patient's ID and name, to check lead quality during hook-up, and to start the recording. During the recording, the keypad can be used to enter event markers. The CM 3000-12BT has a LCD screen to allow ECG display during the hook-up, lead quality check, system configuration and various messages for the hook-up technician. The CM 3000-12BT uses one or two AA batteries, and a removable memory card for data storage.

ECG data and patient data can be transmitted via a Bluetooth connection (BT module from Amber wireless GmbH) from the CM 3000-12BT to CardioDay® and also from CardioDay® to the CM 3000-12BT.

Comparison of Device Technological Characteristics to Predicate Device:

The CG-7000DX-BT, the CardioMem® CM 3000-12 Holter recorder, and the CardioMem® CM 3000-12 Holter recorder have the following technology specifications:

Specification	Legally Marketed Device CG-7000DX-BT ECG Recorder/Transmitter (K052556)	Legally Marketed Device CardioMem® CM 3000-12 (K051086)	New / Modified Device CardioMem® CM 3000-12BT
Online data monitoring	Yes	No	No
Patient hookup	10 ECG electrodes	10 ECG electrodes	10 ECG electrodes
Number of ECG channels derived	12	12	12
ECG lead names	RA, LA, LL, RL, V1, V2, V3, V4, V5, V6	RA, LA, LL, RL, V1, V2, V3, V4, V5, V6	RA, LA, LL, RL, V1, V2, V3, V4, V5, V6
A to D sample rate	720 samples/sec	1024 samples/sec	1024 samples/sec.
A to D resolution	12 bit	12 bit	12 bit
Pacemaker detection	Not specified	No	Yes
Open-Lead detection	Not specified	Yes	Yes
Memory type	Not specified	CompactFlash™ Memory Card	CompactFlash™ Memory Card
Data transfer method	Via Bluetooth connection	Via removable memory card	Via removable memory card
Online data transfer	Via Bluetooth connection	Via OptoLink cable OL1000	Via Bluetooth connection or USB connection
Memory card data format	Not specified	Standard file system	Standard file system
Liquid crystal display (LCD)	Yes	Yes	Yes
Display purpose	Display ECG, Device control	Display ECG, check lead quality, input patient ID, display messages	Display ECG, check lead quality, input patient ID, display messages
Keyboard	Protected touch keys (membrane)	Protected touch keys (membrane)	Protected touch keys (membrane)
System configuration	Not specified	Check lead quality, input patient ID and name, start recording	Check lead quality, input patient ID and name, start recording
System configuration method	Per keyboard and LCD display	Per keyboard and LCD display	Per keyboard and LCD display
Marker button	No	Yes	Yes
Size	Not specified	108 * 86 * 22 mm	108 * 86 * 22 mm
Weight	Not specified	< 160 g (without battery)	<160 g (without battery)
Belt clip / Carrier pouch	Not specified	Carrier bag (Pouch)	Carrier bag (Pouch)
Battery	Not specified	1 or 2 x 1.5 V AA alkaline	1 or 2 x 1.5 V AA alkaline
Battery check prior to recording	Not specified	Yes	Yes
External patient cable	Yes	Yes	Yes
Recorder identification procedure	Not specified	Yes	Yes
ECG channel preview	Yes	Yes	Yes

Intended use:

The CardioMem® digital Holter recorder is intended to continuously record up to 48 hours of ECG data on a digital flash memory card. The CardioMem® performs no cardiac analysis by itself and is intended to be used with the analysis evaluation software CardioDay®. The recorded data are downloaded to a PC for analysis and following evaluation by a trained physician or health care professional.

Federal law restricts CardioMem® to use on order of a physician.

This device is available only upon the order of a physician or other licensed medical professional.

Non-Clinical Testing:

Verification and validation test plans were completed in accordance with getemed AG procedures and GMP guidelines. A Hazard Analysis was completed and hazards were resolved as appropriate.

The CardioMem® CM 3000-12BT complies to the following standards:
- IEC 60601-1,
- IEC 60601-1-1,
- IEC 60601-1-2 (EMC),
- IEC 60601-1-4,
- IEC 60601-2-47,
- IEC 60601-2-51 (Part 50.101.2),
- ANSI/AAMI EC 38,
- ISO 14971,
- EN 980,
- ISO 15223,
- EN 1041

All system specifications were met and testing performed to demonstrate substantial equivalence.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence of safety and effectiveness.

Conclusion:

The CardioMem® CM 3000-12BT Holter recorder is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2007

Getemed AG
c/o Sid Mathur
Senior Regulatory Affairs Specialist
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K063042
Trade/Device Name: CardioMem CM 3000-12BT
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: April 23, 2007
Received: May 3, 2007

Dear Mr. Mathur:

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,

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

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: CardioMem® CM 3000-12BT

Indications For Use:

The CardioMem® CM 3000-12BT is a Holter recorder which is indicated for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063042