K051686
p 1/3

| Abbreviated 510(k) Notification | getemed |
|---|---|
| CardioMem® CM 3000-12 | Project ID: 0404H1 |
| 510(k) - Summary | Section 16-0001-Rev B |

## 510(k) - Summary

JUL 14 2005

**Submitted By:**
getemed AG
Oderstr. 59
14513 Teltow
Germany
Tel.: +49 3328 – 3942-0
Fax: +49 3328 – 3942-99

**Contact:**
Dr. Bert Schadow
Regulatory Affairs Manager

**Manufacturing Facility:**
getemed Medizin- und Informationstechnik AG
Oderstr. 59
14513 Teltow
Germany

**Date of Preparation:** 2005-05-25

**Trade Name:** CardioMem® CM 3000-12 Holter recorder

**Common Name:** Holter recorder

**Classification Name:** Electrocardiograph, ambulatory (without Analysis)

**Product Classification:** 21 CFR 870.2800, Class II

**Product Code:** MWJ

**Legally Marketed Devices:**
DR180+ Holter recorder (**K004007**, NorthEast Monitoring, Inc.)

H12+ Holter recorder (**K021373**, Mortara Instrument, Inc.)
CardioID+ (RZ 153+) Holter recorder (**K022540**, Rozinn Electronics, Inc.)

### Reason for Submission

Premarket notification (Abbreviated 510(k)) for CardioMem® CM 3000-12, a New Device, seeking authority to market the device under Section 510(k) as a device that is substantially equivalent to the DR180+ Holter recorder (K004007, NorthEast Monitoring, Inc.), the H12+ Holter recorder (K021373, Mortara Instrument, Inc.) and CardioID+ (RZ 153+) Holter recorder (K022540, Rozinn Electronics, Inc.).

### Device Description

The CM 3000-12 is a Holter recorder designed to be used in conjunction with the evaluation software CardioDay® (not included in this 510(k)). This recorder is not capable of any diagnosis nor can it provide any interpretation of the data. The CM 3000-12 acquires, digitizes and stores data to be analyzed by CardioDay®. The CM 3000-12 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 3000-12 Holter recorder stores 12 ECG channels continuously for up to 48-hours. 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 3000-12 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 3000-12 uses one or two AA batteries, and a removable memory card for data storage.

### Intended use

The CardioMem® CM 3000-12 digital Holter recorder is intended to continuously record up to 48 hours of ECG data on a digital flash memory card. The CardioMem® CM 3000-12 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® CM 3000-12 to use on order of a physician.

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

### Indications for use

The CardioMem® CM 3000-12 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.

### Comparison of Technology Characteristics

The CardioMem® CM 3000-12 Holter recorder, the DR180+ Holter recorder, the H12+ Holter recorder, and the CardioID+ (RZ153+) Holter recorder have the following technology specifications:

| Specification | Legally Marketed Device DR180+ Holter recorder | Legally Marketed Device H12+ Holter recorder | Legally Marketed Device CardioID+ (RZ153+) | New Device CardioMem CM 3000-12 |
|---|---|---|---|---|
| Online data monitoring & alarm | No | No | No | No |
| Patient hookup | 10 ECG electrodes | 10 ECG electrodes | 7 ECG electrodes | 10 ECG electrodes |
| Number of ECG channels derived | 12 | 12 | 3 | 12 |
| ECG lead names | RA, LA, LL, RL, V1, V2, V3, V4, V5, V6 | RA, LA, LL, RL, V1, V2, V3, V4, V5, V6 | Holter configuration per AAMI EC38 | RA, LA, LL, RL, V1, V2, V3, V4, V5, V6 |
| A to D sample rate | 720 samples/sec. | 180 samples/sec. | 1024 samples/sec. | 1024 samples/sec. |
| A to D resolution | 12 bit | 20 bit | 12 bit | 12 bit |
| Pacemaker detection | Yes | Yes | Yes | No |
| Open-Lead detection | not specified | Yes | Yes | Yes |
| Memory type | CompactFlash™ Memory Card | CompactFlash™ Memory Card | CompactFlash™ Memory Card | CompactFlash™ Memory Card |
| Data transfer method | Via removable memory card | Via removable memory card | Via removable memory card | Via removable memory card |
| Memory card data format | Standard file system | Standard file system | Standard file system | Standard file system |
| Liquid crystal display (LCD) | Yes | Yes | Yes | Yes |
| Display purpose | Display ECG, check lead quality, input patient ID, display messages | Display ECG, check lead quality, input patient ID, display messages | Display ECG, check lead quality, input patient ID, display messages | Display ECG, check lead quality, input patient ID, display messages |

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| Specification | Legally Marketed Device DR180+ Holter recorder | Legally Marketed Device H12+ Holter recorder | Legally Marketed Device CardioID+ (RZ153+) | New Device CardioMem® CM 3000-12 |
|---|---|---|---|---|
| Keyboard | Protected touch keys (membrane) | Protected touch keys (membrane) | Protected touch keys (membrane) | Protected touch keys (membrane) |
| System configuration | Check lead quality, input patient ID, recording mode, start recording | Check lead quality, input patient ID, start recording | 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 | Per keyboard and LCD display |
| Marker button | Yes | Yes | Yes | Yes |
| Size | 125 x 70 x 25 mm | 64 x 91 x 25 mm | 108 x 79 x 22 mm | 108 * 86 * 22 mm |
| Weight | 142 g (without battery) | 125 g (without battery) | <160 g (without battery) | <160 g (without battery) |
| Belt clip / Carrier pouch | not specified | Carrier bag (Pouch) | Carrier bag (Pouch) | Carrier bag (Pouch) |
| Battery | 1 or 2 x 1.5 V AA alkaline | 1 x 1.5 V AA alkaline | 1 or 2 x 1.5 V AA alkaline | 1 or 2 x 1.5 V AA alkaline |
| Battery check prior to recording | Yes | Yes | Yes | Yes |
| External patient cable | Yes | Yes | Yes | Yes |
| Record identification procedure | Yes | Yes | Yes | Yes |
| ECG channel preview | Yes | Yes | Yes | Yes |

## Conclusion

The CardioMem® CM 3000-12 Holter recorder, the DR180+ Holter recorder, the H12+ Holter recorder, and the CardioID+ (RZ153+) Holter recorder are intended to store continuously ECG Data for a period of at least 24 hours. The CM 3000-12, the DR180+, the H12+, and the RZ153+ do not analyze the data at the time of the recording. The recorded data of the mentioned recorders are downloaded to a PC for analysis and following evaluation by a trained physician or health care professional.

Quality system regulation 21 CFR 820 (outlined by the FDA) is a basis for the development of the CardioMem® CM 3000-12 Holter recorder. This recorder is safe and effective for the application for which it is intended and has been tested (environmental and safety tests, including EMC (Electromagnetic Compatibility) tests, according to the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-25, IEC 60601-2-47 and ANSI/AAMI EC 38:1998 standards) to confirm the safety and efficacy of the recorder.

CardioMem® CM 3000-12 is found to be **substantially equivalent** to the DR180+ Holter recorder (K004007), the H12+ Holter recorder (K021373) and the CardioID+ (RZ153+) Holter recorder (K022540).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Getemed Medizin-und Informationstechnik AG
c/o Ms. Carolann Kotula
MDI Consultants Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K051686
CardioMem® CM3000-12
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: June 20, 2005
Received: June 27, 2005

Dear Ms. Kotula:

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) 276-0295 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

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

Enclosure

K051686

# Indications for Use

510(k) Number (if known):

Device Name: CardioMem® CM 3000-12

Indications For Use:

The CardioMem® CM 3000-12 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 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051686