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JUN 29 2005

510(k) Notification	getemed
CardioDay®	Project ID: 0429S1
510(k) - Summary	Section 1-0001-Rev D

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Submitted By:	getemed Medizin- und Informationstechnik AG Oderstr. 59 14513 Teltow Germany Tel.: +49 3328 – 3942-70 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:	2005-06-13
Trade Name:	CardioDay®
Common Name:	Holter ECG
Classification Name:	Computer, Diagnostic, Programmable
Product Classification:	21 CFR 870.1425, Class II
Product Code:	DQK
Legally Marketed Devices:	Holter for Windows® (K930564, Northeast Monitoring Inc.)

Reason for Submission

Premarket notification for CardioDay® (Version 1.9.5), a New Device, seeking authority to market the device under Section 510(k) as a device that is substantially equivalent to the Holter for Windows® evaluation software (K930564, Northeast Monitoring Inc.).

Intended Use

CardioDay® is a software package that allows a trained physician or health care professional knowledgeable in Holter interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording on digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports.

This device is available only upon the order of a physician or other licensed medical professional and not intended for any ambulatory or home applications.

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

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Indications for Use

CardioDay® is a Holter software 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 such as patients who have recently received pacemakers.

WARNING:
CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values.

Device Description

CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values in graphical form. The physician will be able to review, edit, and print the data collected.

Comparison to Legally Marketed Device

Description	[redacted]	[redacted]
Intended use	Holter for Windows® is Holter monitoring software, designed to perform high-speed data analysis of continuous, long-term electrocardiograms saved in the form of direct recordings on a cassette tape or flash memory card. Holter for Windows® is intended for use as an analysis tool and produces printed reports to be reviewed by a person knowledgeable in Holter interpretation. Federal law restricts Holter for Windows® to use on order of a physician.	CardioDay® is a software package that allows a trained physician or health care professional knowledgeable in Holter interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording on digital flash memory Holter recorder, to download and analyze the data from the recorder, review it and produce printed reports. This device is available only upon the order of a physician or other licensed medical professional and not intended for any ambulatory or home applications. Federal law restricts CardioDay® to use on order of a physician.

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Description	[illegible]	[illegible]
Indications for use	Same as CardioDay®	CardioDay® is a Holter software 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 such as patients who have recently received pacemakers. WARNING: CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values.
Device description	Same as CardioDay®	CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values in graphical form. The physician will be able to review, edit, and print the data collected.
Target population	Same as CardioDay®	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 such as patients who have recently received pacemakers.
Design / materials	Same as CardioDay®	CardioDay® is a software package which is delivered on CD.
Sterility	This section does not apply.	This section does not apply.
Biocompatibility	This section does not apply.	This section does not apply.
Mechanical safety	This section does not apply.	This section does not apply.
Chemical safety	This section does not apply.	This section does not apply.
Anatomical sites	This section does not apply.	This section does not apply.

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Description	Holter for Windows®	CardioDay®
Human factors	Same as CardioDay®	Human factors engineering: - device technology (see comparison of technology characteristics), - the users (see target population), - environment in which the technology will be used (see intended use), - how dangerous is the use of the device (see level of concern in section 2), - how critical is the device for patient care (see product classification and level of concern in section 2).
Energy used and/or delivered	This section does not apply.	This section does not apply.
Compatibility with environment and other devices	See comparison of technology characteristics and miscellaneous	See comparison of technology characteristics and miscellaneous
Where used: hospital, home, ambulance, etc.	Holter for Windows® is available for sale only upon the order of a physician or other related licensed medical professional.	CardioDay® is available for sale only upon the order of a physician or other related licensed medical professional and not intended for any home use applications.
Electrical safety	This section does not apply.	This section does not apply.
Thermal safety	This section does not apply.	This section does not apply.
Radiation safety	This section does not apply.	This section does not apply.

Comparison of Technology Characteristics Compared to Legally Marketed Device:

Specifications	Holter for Windows®	CardioDay®
Type	IBM PC AT compatible	IBM PC AT compatible
CPU	Pentium II Processor	Pentium III, 500MHz or greater
RAM	32 Mbytes minimum	128 Mbytes minimum, 256 Mbytes minimum for XP
Free hard disk space	200 MB minimum	5 GB minimum 20 GB for 12-lead recordings
Display	VGA, 14", 1024 x 768 pixel, 256 colors	17" CRT or 15" TFT, 1024 x 768 pixel (XGA), 256 colors
Disc drive / floppy drive	1.4 Mbytes	Not required

Specifications	[illegible]	[illegible]
CD-ROM drive	For installation only	For installation only. Needs to be replaced by a CD-ROM writer or DVD writer if archive option implemented
Operating system	Windows 98	Windows 98 SE, NT (SP6a), 2000 or XP
Ports	One free parallel port	1 parallel port sufficient; if USB devices used for printing, software key or card reader, then corresponding USB ports required
Printer	Printer as any Windows™ compatible	Printer as any Windows™ compatible, 300 dpi
Keyboard	Standard device	Standard device
Mouse	Standard, 2-button device	Standard, 2 or 3-button device
Installation media	(1) CD	(1) CD
Further periphery	Compact Flash card reader	CompactFlash (Type I) memory card reader

Comparison of Software Characteristics:

Patient Screen	[illegible]	[illegible]
Patient Identification Number	Yes	Yes
Patient Name, Address, Telephone	Yes	Yes
Patient Personal Data (Age, Gender, Date of Birth, etc.)	Yes	Yes
Medication	Yes	Yes
Indication	Yes	Yes
Physician's Name	Yes	Yes
Date of Recording	Yes	Yes

Analysis Options	[illegible]	[illegible]
Analysis Duration	Yes	Yes
Primary Channel Selection	Yes	Yes
Sensitivity / Signal Quality	Yes	Yes
Tachycardia Threshold [bpm]	Yes	Yes
Bradycardia Threshold [bpm]	Yes	Yes
Pause Duration [ms]	Yes	Yes
SV Prematurity [%]	Yes	Yes
V Prematurity [%]	Yes	Yes
R on T [ms]	Yes	Yes
Pacemaker Type	Yes	Yes
Minimum Pulse Rate [bpm]	Yes	Yes
Maximum Pulse Rate [bpm]	Yes	Yes
Superimposition / QuickScan	Yes	Yes

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Analysis Options	Predicate Device Holter for Windows	New Device CardioDay
12-Lead ECG Module	Yes	Yes
Holter Data Transfer	Yes	Yes

Events Detected	Predicate Device Holter for Windows	New Device CardioDay
Burst	Yes	Yes
VES / VPB (Extrasystole)	Yes	Yes
SVES / SVPB (Supraventricular Extrasystole)	Yes	Yes
Couplet / VPB Pair	Yes	Yes
Triplet	Yes	Yes
VTACH / VTAC (Ventricular Tachycardia)	Yes	Yes
Bigeminy	Yes	Yes
R on T	Yes	Yes
ST-Analysis	Yes	Yes
SVTACH / SVT (Supraventricular Tachycardia)	Yes	Yes
Arrhythmia / Irregular R-R	Yes	Yes
Bradycardia	Yes	Yes
VTACH (with 4 Beats) / Burst	Yes	Yes
V. STIM / V. Paced	Yes	Yes
A. STIM / A. Paced	Yes	Yes
AV. STIM / AV Paced	Yes	Yes
Undersense / Sense Failure	Yes	Yes
Exitblock / Capture Failure	Yes	Yes
Oversense / Inhibition	Yes	Yes
Pause / Arrest	Yes	Yes
Event Marker	Yes	Yes
HR Stripes	Yes	Yes
Artifact	Yes	Yes
Normal	Yes	Yes

Functionality Available **The comparison between the legally marketed device and the NEW DEVICE is based on their functions only and not on their names.**	Predicate Device Holter for Windows	New Device CardioDay
Start	Yes	Yes
Read Tape	Yes	Yes
Read Digital Recorder	Yes	Yes
Import	Yes	Yes
Analyze New	Yes	Yes
Open	Yes	Yes
Edit Patient Data	Yes	Yes
Print Preview	Yes	Yes
Print	Yes	Yes
Close Recording	Yes	Yes
Close	Yes	Yes

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Functionality Available	Legally Marketed Device Holter for Windows	NEW DEVICE CardioDay
Delete Recording	Yes	Yes
Archive	Yes	Yes
Diagnosis	Yes	Yes
View ECG	Yes	Yes
Print Preview	Yes	Yes
Screen Scale Calibration	Yes	Yes
Screen: Colour Setup	Yes	Yes
FFT Setup	Yes	Yes
Report Setup	Yes	Yes
Classes Display	Yes	Yes
PM Events Display	Yes	Yes
Events Display	Yes	Yes
HR Min./Max. Display	Yes	Yes
Statistics Display	Yes	Yes
Diagnosis Display	Yes	Yes
Overview Display	Yes	Yes
Context sensitive Help	Yes	Yes
Keyboard Shortcuts Help	Yes	Yes
Menu Entries Help	Yes	Yes
Help: About	Yes	Yes
Help: Version	Yes	Yes

Icons/Buttons Available **The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and form of the icons / buttons, however, are different. It might even take more than one click to initiate a given action.**	Legally Marketed Device Holter for Windows	NEW DEVICE CardioDay
Start: Read Digital Recorder	Yes	Yes
Start: Read Tape Recorder	Yes	Yes
Start: Open Existing Record	Yes	Yes
Digital Recorder	Yes	Yes
Tape Recorder	Yes	Yes
Open: List of Patients	Yes	Yes
Print	Yes	Yes
Rhythm Analysis	Yes	Yes
Print Preview on Screen	Yes	Yes

Options Available **The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The name of those options may vary.**	Legally Marketed Device Holter for Windows	NEW DEVICE CardioDay
Classes	Yes	Yes
Events	Yes	Yes
Heart Rate Min/Max	Yes	Yes

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Options Available	Legally Marketed Device Holter for Windows	New Device CardioDay
Average Heart Rate	Yes	Yes
Statistics: FFT Analysis	Yes	Yes
Statistics: ST Diagrams	Yes	Yes
Report	Yes	Yes
Overview	Yes	Yes
Heart Variability: RR Delay	Yes	Yes
Heart Rate Variability: RR FFT	Yes	Yes
Heart Rate Variability: 24h RR FFT	Yes	Yes
Heart Rate Variability: RR Histograms	Yes	Yes

Graphics & Displays Available **The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and appearance of those displays may vary.**	Legally Marketed Device Holter for Windows	New Device CardioDay
Classified Beats Grouped into Morphology Bins	Yes	Yes
Zoomed Version of Selected Beat	Yes	Yes
Context of Selected Beat	Yes	Yes
Events	Yes	Yes
Heart Rate Trend in Recording Period	Yes	Yes
Average RR Interval	Yes	Yes
Y-T Distribution	Yes	Yes
RR > 50ms Distribution	Yes	Yes
FFT Analysis	Yes	Yes
ST Diagrams	Yes	Yes
Overview 2 channels at Different Scaling Factors	Yes	Yes

Printout Options **The following comparison between the legally marketed device and the NEW DEVICE is based on their functionality only. The commands to generate a given printout as well as its appearance do vary.**	Legally Marketed Device Holter for Windows	New Device CardioDay
Full Disclosure 2 Channels, 1 h/Page	Yes	Yes
Full Disclosure 2 Channels, 15 min./Page	No	Yes
Full Disclosure 2 Channels, 30 min./Page	Yes	Yes
Marked Events: 8 Events/Page	Yes	Yes
Marked Events: 32 Events/Page	Yes	Yes
Marked Events: Analysis Channel 25 mm/s	Yes	Yes
Marked Events: Analysis Channel 2.5 min + 25mm/s	No	Yes
Selected Channels 25 mm/s	Yes	Yes
Selected Channels 1 min. + 25 mm/s	Yes	Yes
Selected Channels 2.5 min. + 25 mm/s	No	Yes
Selected Channels 10 min. + 25 mm/s	No	Yes
Event Table	Yes	Yes

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Printout Options	Legally Marketed Device Holter for Windows	New Device CardioDay
Event Histogram	Yes	Yes
Heart Rate and ST Diagrams	Yes	Yes
HR diagram + Min/Max per Minute	No	Yes
RR Intervals	Yes	Yes
RR Delay	No	Yes
RR Histograms	No	Yes
RR Interval Spectra	No	Yes
Pacemaker Event Histogram	Yes	Yes
Pacemaker Function Analysis	Yes	Yes
Report	Yes	Yes
Print to File (PDF)	Yes	Yes
Save as Default Option	Yes	Yes

Editing & Reviewing Options **The following comparison between the legally marketed device and the NEW DEVICE is based on their functions only. The label and appearance of those options may vary.**	Legally Marketed Device Holter for Windows	New Device CardioDay
Scroll through all Beats in a Morphology Bin	Yes	Yes
Edit all Beat Labels in a Morphology Bin	No	Yes
Scroll through ECG and Edit Single Beat Labels	No	Yes
Scroll through Events of the Same Type	Yes	Yes
Edit Event Marker	Yes	Yes
View Patient Event Markers	Yes	Yes
Jump from any Statistics Diagram to the corresponding ECG	No	Yes
Jump from ECG Overview to the corresponding ECG	Yes	Yes
Select Tme Interval for Time Domain RR Parameters	Yes	Yes
Edit Report	Yes	Yes

Miscellaneous	Legally Marketed Device Holter for Windows	New Device CardioDay
RZ153+ Digital Recorder Supported (K022540)	Yes	Yes
CardioMem® CM 3000 (SMA) Supported	Yes	Yes
CardioMem® CM 3000-12 Supported	No	Yes
CD Installation Medium	Yes	Yes
RZ151 Analog Recorder Supported	Yes	No
CD Installation Medium	Yes	Yes

Standards Comparison

Standard	Legally Marketed Device Holter for Windows	New Device CardioDay
21 CFR 820 (FDA cGMP Good Manufacturing Practice)	Yes	Yes

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Standard	Legally Marketed Device Holter for Windows	New Device CardioDay
ISO 9001:2000 / EN 46001 / ISO 13485:2003 Quality Management Systems	Yes	Yes
IEC 60601-1-4 + A1 Programmable Electrical Medical Systems	Yes	Yes
ANSI/AAMI EC38 Ambulatory Electrocardiographs	Yes	Yes
IEC 60601-2-47 Particular Requirements for the Safety, including Essential Performance, of Ambulatory Electrocardiographic Systems	Yes	Yes
ISO 14971 +A1 Application of the Risk Management to Medical Devices	Yes	Yes
EN 980 Graphic Symbols for the Marking of Medical Devices	Yes	Yes
EN 1041 Supply of Information by the Manufacturer of a Medical Device	Yes	Yes
ISO 15223 + AMD1 + AMD2 Symbols to be Used with Medical Devices	Yes	Yes

Differences between the Legally Marketed Device (Holter for Windows®) and the New Device (CardioDay®):

Where Used: Hospital, Home, Ambulance, etc.:

CardioDay® clearly excludes home use applications. This has no influence on safety and effectiveness.

Performance

CardioDay® and Holter for Windows® have the following different technology specifications:

Specifications	Legally Marketed Device Holter for Windows	New Device CardioDay
CPU	Pentium II Processor	Pentium III, 500MHz or greater
RAM	32 Mbytes minimum	128 Mbytes minimum, 256 Mbytes minimum for XP
Free hard disk space	200 MB minimum	5 GB minimum 20 GB for 12-lead recordings
Display	VGA, 14", 1024 x 768 pixel, 256 colors	17" CRT or 15" TFT, 1024 x 768 pixel (XGA), 256 colors
Disc drive / floppy drive	1.4 Mbytes	Not required
CD-ROM drive	For installation only	For installation only. Needs to be replaced by a CD-ROM writer or DVD writer if archive option implemented
Operating system	Windows 98	Windows 98 SE, NT (SP6a), 2000 or XP

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Ports	One free parallel port	1 parallel port sufficient; if USB devices used for printing, software key or card reader, then corresponding USB ports required

The minimum hardware requirements, such as CPU, RAM, free Hard disk space, display, CD-ROM drive and ports and supported operating system of CardioDay® correspond to the current state of the art. No influence on safety and effectiveness is expected.

Software characteristics

The new device CardioDay® offers a number of editing and printing options not available in the legally marketed device. No influence on safety and effectiveness is expected.

Miscellaneous

Holter for Windows® does not support the Holter recorder CardioMem® CM 3000-12. No influence on safety and effectiveness is expected.

CardioDay® does not support the RZ 151 analog tape recorder. This technology is no longer state of the art and therefore it is not supported. No influence on safety and effectiveness is expected.

Conclusion

CardioDay® and Holter for Windows® software packages are both used in clinical applications to allow trained physicians or other health care providers to download, review and print electrocardiographic (ECG) data recorded on digital Holter recorders. Both are computerized programs which run under a computer operating system. Both perform a high-speed analysis of the recorded ECG data and use the computer operating system to access the displayed data. CardioDay® has the same analysis modes as Holter for Windows®. The impact of all parameters, especially those specified above, is evaluated with the help of the data bases from American Heart Association (AHA) and Massachusetts Institute of Technology (MIT) and performance evaluations.

WARNING:
CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values.

CardioDay® conforms to Good Manufacturing Procedures outlined by the FDA GMP. This software is safe and effective for the application for which it is intended and has been tested to confirm the safety and efficacy of the software. CardioDay® is found to be **substantially equivalent** to the Holter for Windows® software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

getemed Medizin-und Informationstechnik AG
c/o Mr. Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
Newtown, CT 06470

Re: K051471
Trade Name: CardioDay®
Regulation Number: 21 CFR 870.1425
Regulation Name: Diagnostic Programmable Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 16, 2005
Received: June 17, 2005

Dear Mr. Borsai:

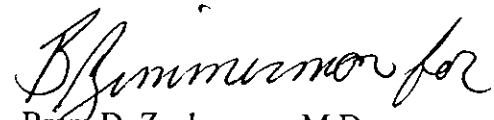
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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/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: CardioDay®

Indications For Use:

CardioDay® is a Holter Software 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 such as patients who have recently received pacemakers.

WARNING:
CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
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