EXELYS

FEB - 4 2011

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K101969

I. Applicant Information

Applicant:

EXELYS LLC
14457 Glorietta Drive
Sherman Oaks, CA 91423
U.S.A.

Contact Person: Ron Wilkerson
President
Tel: (818) 385-0824
Fax: (818) 385-0803
e-mail: ron@exelys.com

Application Correspondent:

EMERGO GROUP INC.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746
U.S.A.

Contact Person: Neal Kolber
Project Manager
Tel: (512) 327-9997
Fax: (512) 327-9998
e-mail: neal@emergogroup.com

Date Prepared: June 7, 2010

II. Device Name and Classification

Proprietary Name:	MH1 MicroHolter Recorder
Classification Name:	Electrocardiograph, Ambulatory (Without Analysis)
Common/Usual Name:	Cardiovascular Monitoring Device
Classification:	Class II
Regulation Number:	870.2800
Product Codes:	MWJ
Classification Panel:	Cardiovascular Devices

EXELYS

III. Predicate Device

The MH1 MicroHolter Recorder device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K071733
Trade Name:	DL900 Series Holter Recorder
Manufacturer:	Braemar, Inc.
Classification Name:	Electrocardiograph, Ambulatory (Without Analysis)
Common/Usual Name:	Cardiovascular Monitoring Device
Classification:	Class II
Regulation Number:	870.2800
Product Codes:	MWJ

IV. Device Description

The MH1 MicroHolter Recorder is a Holter recorder for ambulatory electrocardiogram (ECG) recording. The system consists of three components: a Recorder, a Base Station (computer interface) and the Base Software. The system operates like a conventional ECG monitoring system where data is recorded on Flash memory installed within the MH1 Recorder.

The MH1 MicroHolter Recorder is worn by the patient during ECG monitoring whereas the Base Station is connected to a computer.

After the recording is complete, the MH1 MicroHolter Recorder docks with the Base Station, connected to a personal computer via USB. The Flash memory is then automatically uploaded to the computer via the MH1 Base Software for basic analysis. Data can then be transferred to a Computer Analysis System for further analysis of the recorded ECG data. The MH1, MH1B Base Station and MH1 Base Software are compatible with Windows 98 or higher.

V. Intended Use

The MH1 MicroHolter Recorder is intended for patients requiring ambulatory (Holter) monitoring. Such monitoring is most frequently used for the following indications:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Evaluation of patients for ST segment changes.

- Evaluation of a patient's response after resuming occupational or recreational activities (e.g. after M.I. or cardiac surgery).
- Clinical and epidemiological research studies.
- Evaluation of patients with pacemakers.
- Indication of time and frequency domain heart rate variability.
- Evaluation of patient for QT interval.

VI. Summary of the Technical Characteristics

The MicroHolter Recorder system is primarily a 3 channel recorder designed to be as small and lightweight as possible, using a second hardware component, the Base Station, for data interface with a host computer and contact-less monitoring of the recorded signals for electrode placement purposes.

The recorder converts the three differential inputs into 10 bit digital values which are stored in an internal FLASH memory along with the condition of the annotate button and a parity check bit. Simultaneously, the data values are modulated onto a low frequency carrier signal which is applied to a magnetic loop antenna so that the signal may be picked up at a short distance and converted into a visible waveform on a host computer for verification of electrode lead function.

VII. Testing

EXELYS LLC has conducted extensive validation testing of the MH1 MicroHolter Recorder system, as a cardiovascular monitoring device that is capable of accurately recording and transmitting ECG data. All of the different components of the MH1 MicroHolter Recorder have been tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

VIII. Safety and Effectiveness Conclusions

Based on the comparison of intended use and technological characteristics, the MH1 MicroHolter Recorder system is substantially equivalent to the DL900 Series Holter Recorder manufactured by Braemar, Inc. (K071733). The MH1 MicroHolter Recorder device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Exelys, LLC.
c/o Ms. Caroline Tontini
Project Manager
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746

FEB - 4 2011

Re: K101969
Trade/Device Name: Mh1 Microholter Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: January 5, 2011
Received: January 6, 2011

Dear Ms. Tontini:

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.

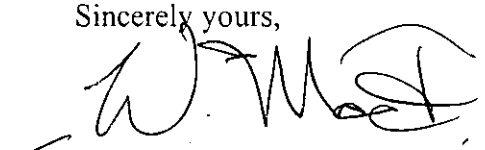
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

4. Indication for Use Statement

510(k) Number (if known): K101969

Device Name: **MH1 MicroHolter Recorder**

Indications for Use:

The MH1 MicroHolter Recorder is intended for patients requiring ambulatory (Holter) monitoring. Such monitoring is most frequently used for the following indications:

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

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

510(k) Number K101969