12. Premarket Notification [510(k)] Summary

Submitted By:

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Contact Person:

Craig Sellers

Prepared June 24th, 2005

Common Name: Electrocardiograph, Ambulatory, With Analysis Algorithm

Trade Name: Matrix Holter System

Classification: 21 CFR 870.2800

Predicate Device: The legally marketed medical devices which are substantially equivalent are:

Mortara H-Scribe Holter Analysis System (K004017)
Mortara H12+ Holter Recorder (K021373)

Burdick PC Holter Scanning System (K945985)

Burdick Altair-Disc Recorder (K942565)

Description:

The M12 Matrix Holter System is a Holter system consisting of the Matrix Holter recorder (M12R) and the PC-based Matrix Holter System Application (M12A). The complete system is referred to as the M12 Matrix Holter System.

The Matrix recorder is a Holter Recorder (ambulatory electrocardiograph) designed to be used with the PC-based Matrix Holter System Application. The Matrix recorder acquires ECG data, converts the data to digital format and stores the digital data. The data is not analyzed by the Matrix recorder. The Matrix recorder uses a 7 or 10 lead electrode hookup and placement to obtain data for use by the Matrix Holter System Application. The Matrix Holter System Application is a PC-based application which is used to analyze, view, print, and edit the data collected by the Matrix recorder. The ambulatory electrocardiograph data recorded by the Matrix recorder is transferred to the Holter System Application, where it is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

The Matrix Holter recorder acquires up to 12 leads of ECG data continuously for a period of up to 48 hours. The data is stored in digital format and is intended to be retrieved from the recorder by the Matrix Holter System Application for data review and analysis.

The Matrix Holter recorder contains a keypad to provide means to configure the recorder, check hookup lead quality, and start the recording. The patient can use the keypad to enter patient activated event marks into the recording.

The Matrix recorder has a display which provides operational status information to the hook-up technician and to the patient. This information includes hook-up lead quality and system status.

The Matrix recorder uses two AA batteries for power supply. Data is stored on a removable memory card. The data is transferred from the Matrix recorder to the Matrix Holter System Application by removing the memory card from the recorder and inserting the card into the memory card interface of the PC running the application. An optional wireless communication interface can also be used to transfer data from the recorder to the Matrix Holter System Application.

The Matrix Holter System Application is a PC-based application. This application runs on a conventional PC system with a processing/data storage module, a graphical color display, a user interface keyboard, a printer, memory card interface and communication interfaces.

Intended Use:

The M12 Matrix Holter System is intended to be used as a Holter ambulatory electrocardiograph system for the purpose of screening for ECG rhythm disturbances over periods up to 48-hours. The Matrix Holter System is intended for use under the supervision of a Physician or those knowledgeable in all aspects of ECG morphology, rhythm and arrhythmia.

This procedure is commonly called a Holter procedure which captures ECG rhythm abnormalities which may be infrequent or provoked by activities outside of the physician office.

The M12 Matrix Holter System is comprised of the Matrix Holter Recorder (M12R) and the Matrix Holter System Application (M12A).

The Matrix Holter Recorder component of the system will be worn by the patient and is used to record ambulatory electrocardiograph data from the patient. The Matrix Holter System Application is used to analyze the data recorded by the Matrix Holter Recorder.

The subject Devices will provide the following diagnostic functions:

- Acquiring, viewing, storing and printing ambulatory ECG waveforms from patients using the Matrix Holter Recorder and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional Holter algorithms to generate measurements, data presentations and graphical presentations on an advisory basis for patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.
- Using optional interpretive algorithms to generate measurements, data presentations, graphical presentations, and interpretive statements on an advisory

basis for patients of sixteen (16) years of age and above. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG data full disclosure displays, and other clinical findings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2005

Global Instrumentation, LLC
c/o Mr. Craig Sellers
Manager of Regulatory Affairs
8104 Cazenovia Road
Manlius, NY 13104

Re: K051730
Trade Name: Matrix Holter System
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, Ambulatory, With Analysis Algorithm
Regulatory Class: Class II (two)
Product Code: MLO
Dated: September 9, 2005
Received: September 12, 2005

Dear Mr. Sellers:

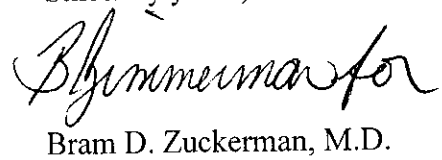
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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



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

Enclosure

11. Statement of Indications For Use

510(k) Number (if known): K051730

Device Name: Matrix Holter System

Indications For Use:

The M12 Matrix Holter System is intended for use by trained operators in health facilities. The subject Device will provide the following diagnostic functions:

- Acquiring, viewing, storing and printing Ambulatory ECG waveforms for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional algorithms to generate measurements, data presentations, and graphical presentations on an advisory basis for the subject patients. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the results of the physical examination, the ambulatory ECG tracings, and other clinical findings.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) or Over-The-Counter Use _____ (Part 21 CFR 807 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 K051730

(Optional Format 3-10-98)