JAN 27 1999

K982384

Mercator 510(k) Summary

Submitter:
Harley Street Software
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Contact Person: Adrian Somers
Date Prepared: May 29, 1998
Device Common Name: Electrocardiograph
Device Trade/Proprietary Name: Mercator
Classification Panel: Cardiovascular

Possible Device Classification Names:
870.2340 Electrocardiograph
870.2450 Medical Cathode-Ray Tube Display
870.1425 Programmable Diagnostic Computer

Predicate Devices:
Cardiomagic Concerto 2000 (K964036)
Synergy (K964784)
Paceart CPTS-86/12 (K915632)

Device Description
Mercator is a software product designed for the Microsoft Windows 95 and Microsoft Windows NT operating systems running on an IBM compatible platform. Mercator consists of a user interface that enables health care professionals to input, store, and output data from a relational database.

The product consists of a set of modules that can be "plugged in" to customize the application to individual users' needs.

Mercator is capable of multi-tasking and supports the linking and embedding of related information objects in the ECG. The software supports many aspects of a patient's cardiology record including: arrhythmia diagnosis, pathological diagnosis, ECGs, ECG information, doctor notes, pacemaker/ICD data and associated reports. Mercator also supports appointment scheduling and stores information on physicians, facilities, allied health care professionals, and insurance providers.

Mercator is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Intended Use of Device
Mercator is intended to be used as a data management tool for physicians and cardiac clinics to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. Mercator is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. Mercator does not offer diagnosis or medical alarms.

Summary of Technological Characteristics Comparison with Predicate Devices
Both Mercator and its predicates are software databases that allow professionals to receive, store, and display electrocardiographs (ECG) recorded from patients by external monitoring devices such as event recorders. All are run on the industry standard IBM compatible platform using industry standard off-the-shelf Microsoft databases. All allow for editing and printing of patient reports that include ECG information and patient demographics. All features of Mercator are present in one or more of the predicates, except the ability to communicate with the ECG recording/transmitting device through an Infra-red data acquisition serial channel (IrDA port), and the ability of the software to automatically answer and receive remote ECG data downloads via modem. IrDA poses the same questions of effectiveness and efficacy as a serial cable, but serves to isolate the patient from any source of electrical shock potential from the PC/computer. Auto-answer has no adverse effect on effectiveness or safety and is aimed solely at satisfying user preferences.

Performance Testing and Conclusions
All software modules were tested at multiple levels including the unit level, post integration, and system level. All modules are tested thoroughly for proper functionality by trained staff using proven techniques. Testing included a combination of manual and automated test suites.

In addition to the above non-clinical testing, the ECG module was tested against the applicable sections of the ANSI/AAMI EC38 – 1994 Standard for Ambulatory Electrocardiographs concerned with effectiveness and safety.

Testing results indicated that the product is safe and reliable. All test plans were passed in accordance with the Mercator Product Release Test Plan.

HarleyStreet Software®

Truthful and Accurate Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as Quality Assurance and Regulatory Affairs Coordinator of Harley Street Software Ltd., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Bruce Webster
(Signature)

Bruce Webster
(Typed Name)

July 7/98
(Dated)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1999

Mr. Craig Person
CardioComm Solutions, Inc.
771 Vanalman Avenue
Victoria, BC
Canada
V8Z 3B8

Re: K982384
Mercator ECG Database Software
Regulatory Class: II (two)
Product Code: DSH
Dated: October 30, 1998
Received: November 3, 1998

Dear Mr. Person:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982384

Device Name: Mercator

Indications For Use:

Mercator is intended to be used as a data management tool for physicians and cardiac clinics to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including Holter and Event Recorder devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. The ECG module may be licensed to other software developers as an ECG viewer for their products. Mercator is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. Mercator does not offer diagnosis or medical alarms.

(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, Respiratory,
and Neurological Devices
510(k) Number K982384

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)