JAN 3 1 2002

CARDIOCOMM
SOLUTIONS INC™

Submitter

Name: CardioComm Solutions Inc.
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Victoria, B.C., Canada
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Contact: Angela Halwas
Date: January 29, 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013354.

Device

Name: GlobalCardio

Substantial Equivalence is claimed to: Mercator (K982384)
Brentwood PC-ECG (K955023)

Description:

GlobalCardio is a cardiology software product, delivered over the web using the Application Service Provider (ASP) model. GlobalCardio operates on IBM compatible PCs and runs within an Internet browser, Microsoft Internet Explorer. GlobalCardio operates as a client server application. GlobalCardio presents an interface for health care professionals to input, store, query and output data from a centrally hosted, or client based relational database.

The product is a web-based database system for the secure storage of all aspects of a patient's cardiology record including: arrhythmia follow-up and diagnosis, trans-telephonic pacemaker follow-up, cardiac rehabilitation data, stress test data pathological diagnosis, ECGs, ECG information, clinical history, physician notes, clinical history and associated reports and queries.

GlobalCardio is a comprehensive ECG management system that is to be sold on a per-use or fee-for-service basis. Software will not be shipped and installed, but rather, customer accounts will be setup for access and record management from the centrally hosted web application. Login IDs and passwords will be created

for each authorized client. All activity on GlobalCardio will be recorded by User ID. User IDs will be provided for each customer to access their own secure database(s). Databases may reside in the secure, firewall protected, warehouse from the application host site, or within an organizations computer network, managed by their own firewall.

GlobalCardio is designed as a multi-user system capable of supporting large volumes of simultaneous users.

Data can be entered via keyboard, mouse, bar code reader, sound card, serial port, or IrDA port, and stored to and retrieved from any computer media. Information can be displayed on the computer monitor or printed.

GlobalCardio 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:

GlobalCardio is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. GlobalCardio will be accessed over the Internet and data will be stored at either the client site or at the central GlobalCardio data warehouse. Data will be secure, and with separate data stores for each client. Users will be able to access specific modules for managing patient cardiac related data such as arrhythmia data that fit their patients' needs. GlobalCardio is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GlobalCardio does not offer diagnosis or medical alarms. 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.

Technological Characteristics:

There are additional features contained in GlobalCardio, which are not available in the predicate devices. These will be explained in the following paragraphs.

GlobalCardio is a web-enabled client/server application designed for setup as an intranet or Internet application. It is web-browser based and has been developed using Microsoft ASP tools. The predicate products do not have these features, as they are traditional desktop PC applications. This architecture enables the GlobalCardio application to function in a new environment (the world wide web, and local Intranets) but in no way changes the clinical aspects of intended use for the product.

GlobalCardio includes the ability to store cardiac rehab information. This feature allows for the collection of patient data as related to protocols defined for a patient involved in cardiac rehab. A physician determines these protocols and GlobalCardio is merely a tool for retaining and reporting this information.

The elements listed in the sections for Security and Audit Tracking pertain only to GlobalCardio. These features provide enhanced security levels exceeding the security available in either of the two predicate devices. These elements ensure that data can only be seen/used by intended persons. The Audit Tracking provides additional security by way of tracking all activity as it pertains to a specific, secure, user ID and session. These enhanced security features enable the GlobalCardio application to function in existing and new PC operating environments but in no way change the clinical aspects of intended use for the product.

GlobalCardio has substantially equivalent indications for use, and similar target population, design, performance, and feature set compared to the predicate devices. GlobalCardio is therefore substantially equivalent to the combination of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2002

Ms. Angela Halwas
Quality System Manager
CardioComm Solutions, Inc.
201 - 3060 Cedar Hill Road
Victoria, British Columbia
Canada

Re: K013354
Trade Name: GlobalCardio
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: January 9, 2002
Received: January 10, 2002

Dear Ms. Halwas:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013354

Device Name: GlobalCardio

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013354

(Optional Format 3-10-98)