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FDA CORE CODE P03

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DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
 2200 Corporate Boulevard  
 Rockville MD 20850

NOV - 1 2005

Datrix, Inc.  
 c/o Mr. Mark Job  
 Regulatory Technology Services, LLC  
 1394 25<sup>th</sup> Street NW  
 Buffalo, MN 55313

Re: K052883  
 Trade Name: Datrix CardioServer ECG Management System  
 Regulation Number: 21 CFR 870.1423  
 Regulation Name: Programmable Diagnostic Computer  
 Regulatory Class: Class II (two)  
 Product Code: DQK  
 Dated: October 10, 2005  
 Received: October 13, 2005

Dear Mr. Job:

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 practices, 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.

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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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrt/industry/support/index.html>.

Sincerely yours,



Brad D. Zuckerman, M.D.

Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Datrix, Inc

Appendix E

Indications for Use Statement

510(k) Number (if known): K052883

Device Name: Datrix ECG Management System

Model: Datrix CardioServer

Indications for Use: The CardioServer ECG Management System software is intended to be marketed to medical professionals and for point-of-care use. The software is designed to provide a database used through out the medical community to store, display, edit and print high resolution ECG data received from devices such as electrocardiographs.

The CardioServer ECG Management System software allows medical professionals responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease to: review and edit specific patient ECG data including intervals such as QT measurements and algorithm generated preliminary interpretative statements. ECG records are all associated by patient ID and other demographic data. Secure access to the database is provided.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

B. L. Williams  
Special Agent  
Office of Cardiovascular Devices  
(k) Number K052883

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Notification Letter

Regulatory Technology Services LLC

Date: November 1, 2005

Jon Barron Inc., dba Datrix  
Linda Gluckman  
340 State Place  
Escondido, CA 92029

Re: CARDIOSERVER

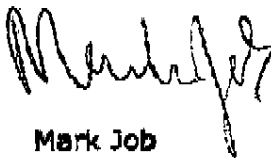
Dear Ms. Gluckman,

This letter is to acknowledge we received via fax the substantial equivalence letter dated November 1, 2005. Congratulations! The original letter will be mailed to you as soon as it is received.

Thank you for choosing Regulatory Technology Services. We look forward to working with you again in the future.

If you have any questions, please do not hesitate to contact me. You may reach me at 763 662 4139.

Sincerely,



Mark Job