K052883

Datrix, Inc

NOV - 1 2005

Appendix G

510(k) Summary of Safety and Effectiveness
for
Datrix, Inc
CardioServer ECG Management System

1. **DATE SUMMARY PREPARED:**
   9-26-2005

2. **SUBMITTER'S NAME AND ADDRESS:**
   Linda Gluckman
   Datrix, Inc
   340 State Place
   Escondido, CA 92029

3. **CONTACT PERSON:**
   Linda Gluckman
   Datrix QA Manager

4. **DEVICE NAME:**

Proprietary (trade) Name:	Datrix CardioServer ECG Management System
Common Name:	ECG Management System
Classification Name:	Programmable Diagnostic Computer/ 870.1425
Product Code:	DQK
Class:	II

5. **PREDICATE DEVICE:** The legally marketed device/s to which equivalence is being claimed is:
   Quinton Pyramis ECG Management System
   3303 Monte Villa Parkway
   Bothell, WA 98021
   K032038

Datrix, Inc

Appendix G

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6. Device Description:

CardioServer ECG Management System is a software only ECG management database that stores, displays, and prints high resolution ECG data transferred from a Datrix Cardio WiFi electrocardiograph device. All ECG records are associated by patient ID, and a final record including physician interpretation can be created.

The software system analyzes data using an ECG analysis algorithm developed under direction of Dr. Peter MacFarlane, University of Glasgow (note: the same algorithm is contained in the predicate device to which equivalency is being claimed). The ECG display is able to show 1, 3, or 12 leads at once, full disclosure, user-selected strips, and interpretations editable by physician. Hardware requirements: are Windows 2000 or 2003 Server operating system; Pentium IV, 2GHz (minimum); 512 MB RAM (minimum); 10/100 Ethernet (minimum); RAID 5 storage; 1024x768 monitor; and standard back-up technology.

7. INTENDED 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 work with ECG Management databases located through out the medical community that commonly store, retrieve, display, edit, and print high-resolution records of ECG data received from devices such as the Datrix Cardio WiFi electrocardiograph.

The CardioServer ECG Management System software allows medical professionals responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease to do the following:

1. Review specific patient ECG data which is available through on-screen display, printer, email, fax, or Hospital Information System (HIS) results which report by interface or other customized data bases.
2. Analyze ECG data using calipers for measurement of various intervals.

The CardioServer system does not modify the original ECG waveform information, but it does provide an automated ECG interpretive analysis of the data.

The ECG data display can show 1, 3, or 12 leads at once, full disclosure, user-selected strips, interpretations (editable by physician), and lists studies using various filters (study type, patient, etc.). Resulting ECG records are

all associated by patient ID and include the physician interpretation.

8. NON-CLINICAL TESTS USED IN DETERMINATION OF SAFETY:
The substantial equivalence of the Datrix ECG Management System is Demonstrated by the following non-clinical testing:

- Testing to the FDA Guidance Document: General Principles of Software Validation; Final Guidance for Industry and FDA Staff.
- Testing for the performance, functionality, and reliability characteristics of the software device followed established test procedures in a quality system.

9. CONCLUSIONS FROM NON-CLINICAL TESTING:
Datrix's CardioServer ECG Management system meets the FDA Guidance Document: General Principles of Software Validation; Final Guidance for Industry and FDA Staff with acceptable results, demonstrating substantial equivalence.

10. Technological Comparison with Predicate:
Both systems:

- Receive ECGs via wireless LAN, LAN, USB2, and other standard transmission modes;
- Store, archive, and display ECGs;
- Export ECGs in industry standard formats to electronic health records;
- Print ECGs;
- Utilize Windows standards;
- Are delivered as software only system;
- Provide secure access to patient health information;
- Log all interaction with patient health information;
- Provide clinical access to ECG data across the users network;
- Utilize the University of Glasgow ECG Algorithm for data interpretation;
- Utilize the University of Glasgow ECG Algorithm for serial comparison of ECGs;
- Allow user editing of ECG interpretation;
- Provide ECG measurements;
- Contain calipers for user edit of ECG measurements;
- Generate management reports such as departmental ECG volume.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2005

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

Re: K052883
Trade Name: Datrix CardioServer ECG Management System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 10, 2005
Received: October 13, 2005

Dear Mr. Job:

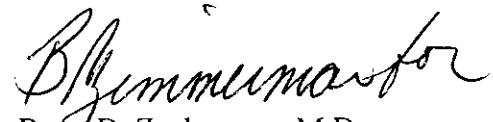
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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) 276-0120. 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 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/industry/support/index.html.

Sincerely yours,



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

Enclosure

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 CDRH, Office of Device Evaluation (ODE)

B Symmons

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sion of Cardiovascular Devices
(k) Number K052883