Datrix, Inc

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NOV 3 0 2005

510(k) Summary of Safety and Effectiveness for Datrix Cardio WiFi Electrocardiograph

1. DATE SUMMARY PREPARED:	SEPTEMBER 26, 2005
2. SUBMITTER'S NAME AND ADDRESS:	Datrix 340 State Place Escondido, CA 92016-1120 Phone: (760) 480-8874 Fax: (760) 480-9474
3. CONTACT PERSON:	Linda Gluckman, QA Manager
4. DEVICE NAME:	
Proprietary (trade) Name:	Cardio WiFi Electrocardiograph
Common Name:	Portable Electrocardiograph without analysis
Classification Name:	Electrocardiograph (CFR 870:2340)
Product Code:	DPS
Class:	2

5. PREDICATE DEVICE:

The legally marketed device/s to which equivalence is being claimed is the CardioCollect Portable Electrocardiograph manufactured by Reynolds Medical, Ltd. (K013367).

6. DEVICE DESCRIPTION

The Cardio WiFi electrocardiograph continuously records data to a flashcard and displays it at high resolution. It features a large, liquid crystal display ("LCD") that allows a medical professional to periodically check the test subject's full, 12-lead ECG, either at intervals or in the event of a patient symptom. The device is portable and is battery-powered.

Data is stored for later review at an ECG review station. Data transfer is accomplished via WLAN 802.11 b or g.

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7. Intended Use

The Cardio WiFi electrocardiograph is a small portable digital electrocardiograph intended for use by medical professionals to acquire 12-lead ECG's from single or multiple patients in a clinical or point of care setting. ECG data is first recorded to a secure digital flashcard and then transferred to an ECG Management System for review by a physician or other qualified professional.

8. Non-clinical Tests Used in Determination of Substantial Equivalence

The substantial equivalence of the Datrix electrocardiograph (Cardio WiFi) is demonstrated by the following non-clinical testing:

- Testing to applicable standards: AAMI EC11, IEC 60601-1; IEC 60601-1-2, IEC 60601-2-25
- Testing for the performance, functionality, and reliability characteristics of the device followed established test procedures in a quality system.

9. Conclusions from Non-clinical Testing

Prior to marketing in the US, the Datrix Cardio WiFi electrocardiograph will have completed the testing listed above with acceptable results, demonstrating substantial equivalence.

10. Substantial Equivalence Conclusion

In summary: Comparison to the predicate device listed in item #5 shows nearly identical technical data, same indications for use, same safety standards tested to, and raises no new questions of safety or efficacy. Therefore, the Datrix Cardio WiFi electrocardiograph supports a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2005

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

Re: K053083
Trade Name: Datrix Cardio WiFi Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: November 14, 2005
Received: November 16, 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,

B/Zuckerman for

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

Enclosure

K053083

Datrix, Inc

Indications for Use Statement

510(k) Number (if known):

Device Name: Datrix Cardio WiFi Electrocardiograph

Model: Datrix Cardio WiFi

Indications for Use: The Cardio WiFi Electrocardiograph is a small portable digital cardiograph intended for use by medical professionals to acquire 12-lead ECG's from single or multiple patients in a clinical or point of care setting. ECG data is first recorded to a secure digital flashcard and then transferred to an ECG management system for review by a physician or other qualified professional.

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)

vision Sign-Off)
vision of Cardiovascular Devices
0(k) Number K053083