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p 1/4

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JAN 13 2006

510(K) SUMMARY

Applicant's Name: CardioSoft, LP
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Houston, Texas 77056

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corporate@CardioSoft.com

Contact Person: Saeed Moradi, Vice-President

Summary Prepared: July 15, 2005

Proprietary Name: CardioSoft® PC ECG

Classification Name: Electrocardiograph

Classification Name: § 870.2340, Electrocardiograph
Product Code: DPS, Class II

Establishment Registration No.: 3003786840

Predicate Device(s): The CardioSoft PC ECG is substantially equivalent to the CARDIAX device, K924544 (Imed / Fairlake Marketing Group) [predicated on the MICROMED QRS-CARD], cleared by prior 510(K) Premarket Notification, in terms of intended use, indications for use, technological characteristics, performance and user interface. The predicate is a Class II device.

Standards: The CardioSoft PC ECG complies with the following recognized voluntary and consensus standards: IEC 60601-1:1988 and amendments, IEC 60601-1-2:2001, IEC 60601-2-25:1999 and amendment, IEC 60601-2-27:1994, ECS53:1995, EC38:1998, UL 2601-1, ANSI/UL 2601-1 ad CAN/CSA C22.2

The device also complies with 21 CFR Parts 801 and 820 for labeling and GMP, and with 21 CFR 898 for electrode lead wires and patient cables.

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K052205

p. 2/4

CARDIOSOFT PC ECG

510(K) SUMMARY

Intended Use / Indications for Use	The CardioSoft PC ECG is intended for use in acquiring, processing, recording, archiving and displaying electrocardiographic information. It can provide serial comparison of ECG information to facilitate review of current and previous records and is intended for use by trained operators. The system offers no diagnostic opinion to the user, but may be used by a physician to render his or her own medical opinion.
Device Description:	The CardioSoft PC ECG is an electrocardiograph that detects signals associated with cardiac activity and produces an ECG graphical record. The device operates on a personal computer through a USB hardware module. The device can acquire, process, record, archive and display 3-, 6-, or 12-lead ECG and vector cardiograms. The device provides portable ECG with important advantages compared to traditional machines. The system requires a USB connection and Windows® operating system and is intended for use by trained operators. It is intended for use by or on the order of a physician or other qualified health care professional. ECGs are routinely used to diagnose cardiac abnormalities, determine response to drug therapy, and reveal changes in heart function. The ECG record data may be utilized only by a qualified healthcare professional for review and interpretation when based upon patient history, medical examination, and other clinical findings.
Technology:	The CardioSoft PC ECG employs the same functional technology as the predicate device. The only differences are technological improvements made with respect to

USB interface, greater frequency response, and use with current Windows® operating systems.

Both devices utilize preamplifiers to collect electrocardiographic information from skin electrodes. The preamplifiers provide electrical isolation of the patient and the device. There are differences in two components that provide electrical isolation. The proposed device uses a different isolation DC/DC converter (made by Recom) and optocoupler (made by Hewlett Packard) than the predicate device. The proposed device utilizes an integrated USB module and provides improved frequency response. Both devices are in compliance with electromagnetic compatibility conformance and electrical and thermal safety compliance by the applicable standards. No energy is delivery to the patient. The enhancements have no effect on safety or performance.

The software processes of the predicate device have been fully preserved in the proposed device and have been adapted for use with the latest versions of the Windows® operating system. Generated data is identical, however the proposed device allows the user to more aptly configure screen display and printer output to a desired format. The enhancements have no effect on safety or performance.

K052295
p 4/4

Performance:

The FDA has not established performance standards for this device. A listing of voluntary or consensus standards is provided in SECTION O – APPENDIX: Attach 5 - CARDIOSOFT PC ECG (USB version) STANDARDS TEST REPORT.

Non-clinical testing has been performed demonstrating equivalence with the predicate device CARDIAX and the results show similar performance with this device. Conformance to the product development procedures and plans have been assured by the application of system tests, design reviews, and product verification and validation testing performed prior to product release.

The following quality assurance measures were applied to the development of the CardioSoft PC ECG :

- Requirements specification reviews
- Code inspections
- Software and hardware evaluation and testing
- Safety testing
- Environment testing
- Final validation

Conclusion:

The CardioSoft PC ECG is an upgrade modification to the predicate device CARDIAX of like design and manufacture. This premarket notification submission demonstrates that the CardioSoft PC ECG is substantially equivalent because this device has the same basic intended use and the differences in technological characteristics do not raise new questions of safety or effectiveness. The CardioSoft PC ECG is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

CardioSoft, LP
c/o Mr. Saeed Moradi
Vice-President
1776 Yorktown Street, Suite LL30
Houston, Texas 77056

Re: K052295
Trade Name: CardioSoft PC ECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: October 24, 2005
Received: November 18, 2005

Dear Mr. Moradi:

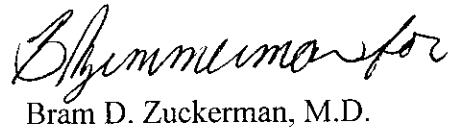
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

Indications for Use

510(k) # (if known): K052295

Device Name: CARDIOSOFT PC ECG

Indications for Use:

The CardioSoft PC ECG is intended for use in acquiring, processing, recording, archiving and displaying electrocardiographic information. It can provide serial comparison of ECG information to facilitate review of current and previous records and is intended for use by trained operators. The system offers no diagnostic opinion to the user, but may be used by a physician to render his or her own medical opinion.

Prescription Use __x___ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052295