K051853

AUG 2 2 2005

cardiostream

510(k) Summary

Submitter Information:

CardioStream
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Contact:

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Date Prepared:

June 3, 2005

Product Name:

CFR Section: 892.2050
Product Code: LLZ
Panel: Radiology

Description:

The CardioStream SonoAim is a clinical assessment tool designed to automate the movement of clinical data through the clinical assessment process. The system is comprised of the following components:

Data Harvester (DH) – Laptop (variations – desktop, pole-mounted LCD screens)
Data Packager (DP) – Computer (tower)
AIM Server – Archive and Image Manager – located at secure off-site data center

Data and images are captured in the clinical setting via an image capture device (DH), and a preliminary report is completed by the Sonographer.

The preliminary report is immediately formatted (DP) and available on a secure web-accessed internet site.

The physician with secure user name and password will then access/review the clinical images and preliminary report, and edit or add commentary as needed.

The final report is then electronically signed and returned to the referring physician. The information is available on any web-accessible device.

Substantial Equivalence:

This device is substantially equivalent to the Siemens KinetDX, marketed under K041029.

	CardioStream SonoAim (Proposed Device)	**KinetDx WS3000 (Predicate Device)**
Image Format	Media Player v.9, WMV, PNG, AVI DICOM 3.0	DICOM 3.0
Compression-Video	Constant or variable bit rate	Dicom convertor – QV3000 For Non-Dicom Images
Compression - Dicom	Uncompressed RLE Lossless Compression JPEG Lossy Baseline JPEG Lossless Non-Heirarchal	Uncompressed RLE Lossless Compression JPEG Lossy Baseline JPEG Lossless Non-Heirarchal
Video Source	S-video, composite DICOM	DICOM
Display	15" – 21" Flat Panel Color Monitor	20" or 21" Flat Panel Color Monitor
Operating System	Windows XP	Windows 2000
User Interface	Keyboard Mouse Foot pedal	Keyboard Mouse
Network	Fast Ethernet 10/100/1000	Ethernet 100/1000
Hardware	Standard Computer Hardware	Standard Computer Hardware
Image Storage Media	Internal Hard Disk Built-in CD-Rom	Internal Hard Disk Built-in CD-Rom
DICOM	Yes – Not required	Yes – Not required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

CardioStream, LLC
% Mr. Ian P. Gordon
Senior Vice President
Emergo Group
2454 McMullen Booth Rd., Suite 427
CLEARWATER FL 33759

Re: K051853
Trade/Device Name: CarioStream SonoAim
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7,, 2005
Received: July 13, 2005

Dear Mr. Gordon:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) # (if known): K051853

Device Name: CardioStream SonoAim

Indications for Use:

The CardioStream SonoAim is intended for capturing, transporting, and reporting patient cardiac study data.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051853