K053062

JAN 6 2006

510(k) SUMMARY

CARDIARC LTD.'s
CARDIARC SPECT IMAGING DEVICE

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED:

CARDIARC LTD.
8200 Nashville Suite 209
Lubbock, TX 79423

Phone: 806-722-2027
Facsimile: 806-722-2029

Contact Person: W. Don Stull, CEO
CardiArc, Inc. General Partner

Date Prepared: October 27, 2005

NAME OF DEVICE: CARDIARC SPECT IMAGING DEVICE

COMMON OR USUAL NAME: SPECT Camera System

CLASSIFICATION NAME: Computed Emission Tomography System

PREDICATE DEVICES:

DIGIRAD 2020tc SPECT Imaging System (K982855)

Segami Corporation Inc.'s Mirage software package (K972886 and K010726)

INTENDED USE / INDICATIONS FOR USE:

The CARDIARC SPECT IMAGING DEVICE and its predicate device is intended to be used for production of single photon emission computed tomography clinical images of the heart in nuclear medicine applications.

The CARDIARC SPECT IMAGING DEVICE is indicated for use to produce images from the distribution of radioisotopes within the thorax, which are then interpreted by healthcare professionals to assess various anatomical structures and functions (*e.g.*, blood flow to the heart).

TECHNOLOGICAL CHARACTERISTICS:

The CARDIARC SPECT IMAGING DEVICE consists of an integrated patient chair which adjusts in height but does not rotate, an arc with no external moving parts, which is constructed of an internal rotating slot collimator, horizontal lead vanes separated by foam spacers, cadmium zinc telluride (CZT) detectors, and electronic components, a power supply, cooling system, and hardware and software components.

Thus, the CARDIARC SPECT IMAGING DEVICE raises no new issues of safety or efficacy.

PERFORMANCE DATA:

Bench testing was performed using NEMA NU1 phantom or equivalent phantoms, under the NEMA or equivalent standard test procedures. In all cases performance of the CARDIARC SPECT device met or exceeded that of predicate devices.

Cardiac Phantom Imaging was used to test the accuracy of reconstruction and identification of simulated myocardial perfusion defects. Results showed that the quality of reconstructed tomographic images of a test phantom obtained by the CARDIARC SPECT IMAGING DEVICE was at least equal to images obtained by predicate reference SPECT system.

Clinical images were obtained using the CARDIARC SPECT IMAGING DEVICE in human subjects. Tomographic image quality was judged to be excellent by the Board-Certified Nuclear Medicine physicians at the investigational center, and was judged to be at least equal to images obtained by the predicate reference SPECT system.

SUBSTANTIAL EQUIVALENCE:

The CARDIARC SPECT IMAGING DEVICE has the same intended use, similar principles of operation and technological characteristics as the predicate device. Furthermore, the CARDIARC SPECT IMAGING DEVICE uses predicate device software for image acquisition, processing and display.

Cardiac phantom and clinical imaging demonstrated that the CARDIARC SPECT IMAGING DEVICE produced images at least equal to images obtained with predicate SPECT devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

CardiArc Ltd.
% Mr. Jonathan Kahan
Partner
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K053062
Trade/Device Name: CardiArch Spect Imaging Device
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: October 28, 2005
Received: November 3, 2005

Dear Mr. Kahan:

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) Number (if known): K053062

Device Name: **CARDIARC SPECT IMAGING DEVICE**

Indications For Use:

The **CARDIARC SPECT IMAGING DEVICE** is intended for production of single photon emission computed tomography clinical images of the heart in nuclear medicine applications. **CARDIARC SPECT IMAGING DEVICE** produces images from the distribution of radioisotopes within the thorax, which are then interpreted by healthcare professionals to assess various anatomical structures and functions (*e.g.*, blood flow to the heart).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053062