K032823

NOV 10 2003

Appendix E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:

Name:	Medicsight PLC.
Address:	46 Berkeley Square London W1J 5AT UK
Telephone:	44 (0) 207 598 4070
Facsimile:	44 (0) 207 598 4071
Contact:	Carol MacDonald, RA QA Manager
Date of summary:	02 September 2003

Device Information:

Trade Name:	MedicHeart™ Release 1
Common Name:	Medical imaging software for CT scanners
Classification Name:	Computed Tomography X-Ray System, Accessory
Regulation Number:	892.1750

Predicate Device:

Medicsight MedicHeart 1 is substantially equivalent to the following devices:

Manufacturer	Device	510(k) No.
GE Medical Systems	SMARTSCORE 3.5; 4.0; 4.5	K020929
VIATRONIX	V3D CALCIUM SCORING	K013146
VOXAR	CALCIUM SCORING PRODUCT	K020140

medicsight

Device Description:

MedicHeart™ is a software tool designed to assist radiologists and other clinicians in the identification and quantification of coronary artery calcification. The software allows the user to manually select Regions of Interest by a single click or a drawing tool followed by semi-automatic detection. It provides calculation of calcium score using the traditional Agatston method, as well as measurement of the volume and mass of calcified plaques.

Intended Use:

MedicHeart 1 is a PC-based, stand-alone, non-invasive, image analysis software application intended to assist radiologists and other clinicians in the identification and quantification of coronary calcified plaques in the coronary arteries from CT image data. This quantification allows for evaluation of the progression or regression of calcified plaques in coronary arteries over time.

Comparison to Predicate Device:

As in the predicate devices, GE SmartScore, Viatronix V3D and Voxar Calcium Scoring, MedicHeart 1 evaluates CT images for the identification and quantification of coronary artery calcified plaques.

Test data are provided to validate the performance of the system and its substantial equivalence to the predicate devices. The functional features and the intended use of MedicHeart 1 are substantially equivalent to the predicate devices.

Safety:

A comprehensive hazard analysis was carried out on MedicHeart 1, which concluded that any residual risks were as low as reasonably practicable and judged as acceptable when weighed against the intended benefits of use of the system.

Conclusion:

MedicHeart 1 does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. MedicHeart 1 is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Ms. Carol MacDonald
Regulatory & Quality Manager
Medicsight
46 Berkeley Square
W1J5AT, London
UNITED KINGDOM

Re: K032823
Trade/Device Name: Medicsight Medic-Heart Release 1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 8, 2003
Received: September 10, 2003

Dear Ms. MacDonald:

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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K032823

Device Name: Medicsight MedicHeart Release 1

Indications for Use:

MedicHeart 1is a PC-based, stand-alone, non-invasive, image analysis software application intended to assist radiologists and other clinicians in the identification and quantification of coronary calcified plaques in the coronary arteries from CT image data. This quantification allows for evaluation of the progression or regression of calcified plaques in coronary arteries over time.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K032823

Prescription Use ✓