K033774

12. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submission in accordance with the requirements of 21 CFR Part 807.87(h)

1. Submitter	: MEDIS medical imaging systems bv
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: December 01, 2003
2. Device Name	: Medis CT-MASS
Common Name	: **CT-MASS**
Device Class. Name	: Computed Tomography x-ray systems
Regulation Number	: 21 CFR 892.1750 (90 JAK; Class II)
3. Predicate Device(s)	: GEMS: 510(k) **K013422; K020796**

4. Description of the device:

CT-MASS is a professional state-of-the-art analytical software tool designed for UNIX, Linux as well as Windows platforms. CT-MASS facilitates the import and visualization of multi-slice, multi-phase CT data sets encompassing the cardiac chambers via CD-Rom and digital network. This CT-MASS functionality is independent of the CT equipment vendor. CT-MASS provides objective and reproducible global and regional two-, three- and four-dimensional clinically relevant parameters describing left and right ventricular heart function, such as ventricular volumes, regional wall thickness and wall thickening/thinning CT-MASS is intended to support all clinicians, i.e. cardiologists, radiologists, and referring physicians involved in the noninvasive assessment of heart function.

5. Intended use:

CT-MASS has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac CT data sets.
The itended purposes are:

1. Supporting clinical diagnoses about the status of the global and regional function and anatomy of the human heart;
2. Supporting the subsequent clinical decision making processes;
3. Supporting the use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of treatment.

6. Substantial equivalence Information:

CT-MASS is substantially equivalent to the Predicate Devices of General Electric Medical Systems, K013422 "CardIQ Function" and K020796 "CardIQ Analysis II", using the same technological technique for the same intended use.

Conclusion respecting safety and effectiveness:

It is the opinion of Medis medical imaging systems bv that CT-MASS is safe and potential hazards are controlled by a risk management plan for the software development process (**See Appendix C**), including hazard analysis (**See Appendix D**), verification and validation tests (**See Appendix E**). Evaluations by hospitals and literature (**See Appendix F**) support this statement. The software package CT-MASS itself will not have any adverse effects on health. This tool calculates and displays the anatomy and function of the left and right ventricles. The ventricular contours and regions-of-interest will be interpreted by the operator, who can choose to accept or reject the outlines, and then decide to use the derived data to compare against earlier images or images from other patients.

It is the opinion of Medis medical imaging systems bv that the level of concern for the stand alone software to view images is 'minor' and that the use of CT-MASS software does not change the intended use of computed tomography scanners in practice, nor does the use of software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2004

Mr. J.I. Hollander
Quality Coordinator
Medis Medical Imaging Systems, B.V.
Schuttersveld 9 2316XG Leiden
P.O. Box 384 2300 AJ Leiden
THE NETHERLANDS

Re: K033774
Trade/Device Name: CT-MASS Analytical Software Package
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: December 1, 2003
Received: December 3, 2003

Dear Mr. Hollander:

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): K033774

Device Name: CT-MASS

Indications For Use:

CT-MASS has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac CT data sets. The CT-MASS software package can be used to semi-automatically calculate and display various parameters such as: EDV, ESV, stroke volume, ejection factor, peak ejection and filling rates, myocardial mass, regional wall thickness, as well as wall thickening/thinning, and regional wall motion. This is including the axial to short axis reformat.

When interpreted by a trained physician these parameters may be useful in supporting the determination of a diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033774