K994283

AUG 3 0 2000

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* B.V.
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: December 15, 1999
2) **Device Name**	: MRI - Magnetic resonance Analytical Software System
Common Name	: **MASS**
Device Class. Name	: System, Image Processing;
Regulation Number	: 21 CFR 892.2050 (90 LLZ; Class II)
3) **Predicate Device(s)**	: Medis: 510(k) **K993765**;

4) Description of the device:

MASS is a professional state-of-the-art analytical software tool designed for UNIX as well as Linux platforms. MASS facilitates the import and visualization of multi-slice, multi-phase MRI data sets encompassing the cardiac chambers via CD-Rom and digital network. This MASS functionality is independent of the MRI equipment vendor. 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 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:

MASS, including its option, has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac MR data sets. The software enables the display of images for use by trained medical personnel.

Intended purposes are:

1. supporting clinical diagnoses about the status of the global and regional function and anatomy of the cardiac chambers;
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 interventions.

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6) **Substantial equivalence Information:**
MASS is substantially equivalent to the Predicate Devices of MEDIS *medical imaging systems* B.V., K993765 "QLV-CMS" (Quantitative Left Ventriculography- Cardiovascular Measurement System)

Conclusion respecting safety and effectiveness:
It is the opinion of MEDIS *medical imaging systems* B.V. that 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 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.
In MEDIS opinion the level of concern for the stand alone software to view images is 'minor' and that the use of MASS software does not change the intended use of magnetic resonance scanners in practice, nor does the use of software result in any new potential hazards.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Mr. J. I. Hollander
Quality Coordinator
MEDIS Medical Imaging Systems B.V.
Poortgebouw Rijnsburgerweg 10
2333 AA Leiden
NETHERLANDS

Re: K994283
MRI-MASS (analytical software)
Dated: June 22, 2000
Received: June 26, 2000
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Mr. Hollander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K994283

Device Name: MASS

Indications For Use:

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994283

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)