MAR - 4 2008

12. SUMMARY OF SAFETY AND EFFECTIVENESS

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

- **Submitter** : Medis medical imaging systems b.v.
  Address : Schuttersveld 9
  : 2316 XG Leiden, The Netherlands
  Telephone : +31 71 522 3244
  Fax : +31 71 521 5617
  Contact Person : J.I. Hollander, Quality Coordinator
  Prepared : February 19, 2008

Device Name : Quantitative analysis of MR images

Common Name : QPlaque MR
  Device Class. Name : Class II; PACS software
  Regulation Number : 21 CFR 892.1000 (90 LNH)

- **Predicate Device(s)** : - Prowin K050376; - SonoCalc K030223; - Plaque View K043111; - Vitrtea K071331; - Viatronix V3D Vascular K033361

- **Device Description**

QPlaque MR is able to read DICOM MR images from all major MR vendors. Vessel analysis data, generated by semi-automatic segmentation, detected stenosis and quantitative results can be saved in separate files enabling the comparison of results from different users.
Radiologists, cardiologists and technicians use the QPlaque MR analytical software package to obtain objective and reproducible results. The obtained results may be used to support the interpretation of MR data, or they are used in the evaluation of follow-up studies and the effectiveness of treatment.
In clinical practice QPlaque MR is used on workstations in review rooms or integrated in a PACS environment.

- **Indications for Use**

The QPlaque MR software performs quantitative analyses of the vessel wall and of plaque components in MR studies of atherosclerotic arteries. The quantitative analyses are based on semi-automatic segmentation of the MR studies. QPlaque quantifies vessel wall and plaque volumes, determines vessel wall thickness, thickness of the fibrous cap, and characterizes the plaque components.
QPlaque MR is intended for use by cardiologists or radiologists as an auxiliary tool in assessing atherosclerotic vessels. Its results may be used to support the decision-making process in clinical practice and to support conclusions in clinical trials.

- **Substantial Equivalence Information**

QPlaque MR is substantially equivalent to the Predicate Devices of Prowin of MTI (**K050376**), SonoCalc of SonoMetric Health (**K030223**), Plaque View of Toshiba (K043111), Vitrea (K071331) and Viatronix V#D of Viatronix (K033361), using the same technique for the same intended use; only MR images instead of Ultrasound and CT images.

Conclusion

In Medis' opinion, QPlaque MR is a safe medical device. During the development, potential hazards were controlled by a risk management plan, including hazard and risk analyses, verification and validation tests. Evaluations by hospitals and literature support this statement. The software package QPlaque MR itself will not have any adverse effects on health. The operator interprets the objective values of the analysis and chooses to accept or reject the results.

The use of QPlaque MR does not change the intended use of MR scanners in practice, nor does the use result in any new potential hazard. Based of the information supplied in this 510(k), Medis conclude that the subject device is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. J. I Hollander
Quality Coordinator
Medis Medical Imaging Systems B.V.
Schuttersveld 9
2316 XG Leiden
NETHERLANDS

MAR - 4 2008

Re: K073156
Trade/Device Name: QPlaque MR
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 19, 2008
Received: February 25, 2008

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 (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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number: K073156

Device Name: **QPlaque MR**

Indication for Use:

QPlaque MR is a post-processing software application that is intended to assist trained cardiologists and radiologists in the assessment of atherosclerosis. The software is intended in particular to aid in assessing vessel wall thickness and remodeling in the carotid arteries I
QPlaque MR post-processes multi-spectral MR images to semi-automatically determine the boundaries of the lumen and outer vessel wall, and provides editing tools for manual drawing of plaque components. The software enables area and volume measurements of the vessel wall as well as quantification of user-indicated areas.
QPlaque MR results can be used to support the decision-making process in clinical practice and to support conclusions in clinical trials.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073156