12. SUMMARY OF SAFETY AND EFFECTIVENESS

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

OCT - 5 2006

• **Submitter**	: Medis medical imaging systems bv
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: August 10, 2006
• **Device Name**	: Automatic quantitative analysis of CTA images
Common Name	: QAngio® CT
Device Class. Name	: Class II; PACS software
Regulation Number	: 21 CFR 892.1750 (90 JAK)
• **Predicate Device(s)**	: MRA-CMS, **K040746**

• **Device Description and indications for Use**

QAngio CT is able to read DICOM CT images from all major CT scanner vendors. Vessel analysis data, generated by automated (and/or manual) 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 QAngio CT analytical software package to obtain objective and reproducible results. The obtained results may be used to support the interpretation of CTA data, or they are used in the evaluation of follow-up studies and the effectiveness of treatment.
In clinical practice the QAngio CT software is used on workstations in review rooms or integrated in a PACS environment..

• **Intended use**

The QAngio CT software solution has been developed for the objective and reproducible analysis of vessels in CTA images. It enables the quantitative analysis of CT angiograms based on automated segmentation. More specifically, QAngio CT can be used to quantify a number of lesion characteristics.

QAngio CT is intended for use as an auxiliary tool in assessing CTA studies in clinical practice and in clinical trials. The analysis results obtained with QAngio CT are to be interpreted by cardiologists or radiologists.

• **Substantial equivalence Information**

QAngio CT is substantially equivalent to the Predicate Device of MRA-CMS, K040746, using the same technique for the same intended use; only CT- instead of MR images.

Conclusion

In Medis' opinion, QAngio CT 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 information support this statement. The software package QAngio CT 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.
In current thinking, the level of concern for the standalone software in image post-processing is 'Minor' and the use of QAngio CT does not change the intended use of CT scanners in practice, nor does the use result in any new potential hazard.
Based on the information supplied in this 510(k), Medis concludes that the subject device is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 5 2006

Mr. J. I. Hollander
Quality Coordinator
Medis Medical Imaging Systems bv
9 Schuttersveld
Leiden
The Netherlands 2316XG

Re: K062386
Trade/Device Name: QAngio CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Dated: August 11, 2006
Received: August 16, 2006

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

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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 (if known): K062386

Device Name: **QAngio CT**

Indications For Use:

QAngio CT software solution has been developed for the objective and reproducible analysis of vessels in CTA images. It enables the quantitative analysis of CT angiograms based on automated segmentation. More specifically, QAngio CT can be used to quantify a number of lesion characteristics.
QAngio CT is intended for use as an auxiliary tool in assessing CTA studies in clinical practice and in clinical trials. The analysis results obtained with QAngio CT are to be interpreted by cardiologists and radiologists.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

David G. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062386