K994282

MAR - 2 2000

MRI - FLOW
510(k) Premarket Notification

12 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

1) **Submitter** : MEDIS m*edical imaging systems* B.V.
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Contact Person : J.I. Hollander, Quality Coordinator
Prepared : December 15, 1999

2) **Device Name** : MRI – FLOW analytical software package
Common Name : **FLOW**
Device Class. Name : System, Image Processing;
Regulation Number : 21 CFR 892.2050 (90 LLZ; Class II)

3) **Predicate Device** : General Electric: 510(k) **K924605**

4) **Description of the device:**
FLOW is a state-of-the-art analytical software tool designed for UNIX as well as Linux platforms. FLOW facilitates the import and visualization of velocity-encoded cine MRI imaging studies via CD-ROM and digital network. This FLOW functionality is independent of the MRI equipment vendor. FLOW provides objective and reproducible data on velocity and volume flow as a function of time, and other derived data such as mean velocity and volume flow, stroke volume and cardiac output. FLOW is intended to support all clinicians, i.e. cardiologists, radiologists, and referring physicians involved in the noninvasive assessment of flow and flow velocity in arterial vessels and at heart valves.

5) **Intended use:**
FLOW has been developed for the objective and reproducible analysis of velocity-encoded cine MR imaging studies of arterial vessels and heart valves. Intended purposes are:

1. supporting clinical diagnoses about the status of the function of the cardiac cambers;
2. supporting clinical diagnoses about the flow velocity and volume flow through cardiac and peripheral vessels, both under basal and increased flow conditions;
3. supporting subsequent clinical decision making purposes;
4. supporting the use in clinical research trials, directed at studying changes in function of the heart chambers and in the flow through cardiac and peripheral vessels as a result of interventions.

6) **Substantial equivalence Information:**
The FLOW software is substantially equivalent to the predicate devices of General Electric K924605 "Flow Analysis Option for Advantage Windows™ 2.0 and 3.1" by using the same technological characteristics and intended use.

Conclusion respecting safety and effectiveness:
It is the opinion of MEDIS *medical imaging systems* B.V. that FLOW 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**). Evaluation by hospitals and literature (**see Appendix F**) support this statement.
In MEDIS opinion the level of concern for the standalone software to view images is 'minor' and that the use of FLOW 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2000

J.J. Hollander
Quality Coordinator
Medis Medical Imaging Systems, B.V.
Poortgebouw, Rijnsburgerweg 10
2333 AA Leiden
The Netherlands

Re: K994282
MRI-FLOW Analytical Software Packager for MRI
Dated: December 16, 1999
Received: December 20, 1999
Regulatory class: II
21 CFR 892.1000/90 LNH

Dear Mr. Holland:

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
Acting 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): K994282

DEVICE NAME: MRI-FLOW Analytical Software Package

INDICATIONS FOR USE:

FLOW has been developed for the objective and reproducible analysis of velocity-encoded cine MR imaging studies of arterial vessels and heart valves. The FLOW software package enables to semi-automatically calculate and display of various parameters such as: Mean velocity (also minimum, maximum and standard deviation) and volume flow in different region of interest (ROI); Velocity and volume flow as function of time; Stroke volume and cardiac output. 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)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use___ (Optional Format 1-2-

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994282