

QLV-CMS Special 510(k) Notification "Device Modification" SUMMARY
510(k) Summary of safe and effectiveness information conform 21CFR. 807.87(h).

1) Submitter : MEDIS Medical Imaging Systems, Inc.,
Address : 109 Danbury Road
Ridgefield, CT 06877 USA
Telephone : 203.438.5588
Fax : 203.438.5393
Contact Person : Douglas Orr, President
Prepared : July 30, 1999
2) Device Name : Quantitative Analysis of Left Ventricular Angiograms (QLV)
Common Name : QLV-CMS
Device Class. Name : System, X-ray, Angiographic
Regulation Number : 21 CFR 892.1600 (90 IZI; Class II)

3) Predicate Device(s) : Cardiovascular Measurement System - (CMS)
510(k) Number: K940172

4) Description of the device:

QLV-CMS performs quantitative analysis of angiograms (specific to the left ventricle) that are input to the system in formats that include digitized video (from 35 mm cinefilm) and DICOM-file standard formats. The analysis results of the QLV-CMS operation may be printed or archived in files for export to a general-purpose database.

5) Intended use:

QLV-CMS allows the user to work productively in the increasingly digital world of images that are archived in DICOM formats as a result of angiography procedures. The QLV-CMS product is used to select images of the left ventricle for quantitative analysis, resulting in measurements of the selected images. The quantitative information is provided for use by physicians and scientists in both research and clinical settings. Image archiving and administration purposes are supported with the QLV-CMS product as well.

6) Substantial equivalence information:

The QLV-CMS software, as a software package, is substantially equivalent to the predicate device "Cardiovascular Measurement System - CMS" by utilizing the same technical standards and image analysis algorithms for efficient, accurate and reproducible results. The differences in the devices are noted as:

- a. QLV-CMS now runs on Windows NT, as compared with the predicate device operation on MS-DOS, and
- b. QLV-CMS is a modular software package, as compared with the fully-integrated predicate device. Image handling (review, playback, selection) may now be accomplished with other modular software packages, including the CMS-View from MEDIS.

Conclusion respecting safety and effectiveness:

It is the opinion of MEDIS medical imaging systems that QLV-CMS is safe and potential hazards are controlled by a risk management plan for the software development process, including hazard analysis, verification and validation tests and evaluations by hospitals. In our opinion the level of concern for stand-alone software to analyze images is "minor" and that the use of QLV-CMS software does not change the intended use of the angiographic systems in practice.



NOV 26 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Douglass Orr
President
MEDIS Medical Imaging Systems, Inc.
109 Danbury Road
Ridgefield, CT 06877

Re: K993765
Quantitative Analysis of Left Ventricular
Angiograms – Cardiovascular
Dated: July 30, 1999
Received: November 8, 1999
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Orr:

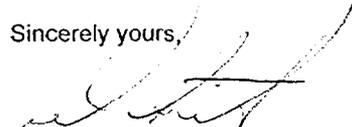
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4613. 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" (21 CFR 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,



Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page ____ of ____

510(k) Number (if known): K993765

Device Name: _____

Indications For Use:

510(k) Number: K993765
Device Name: Quantitative Analysis of Left Ventricular Angiograms (QLV-CMS)

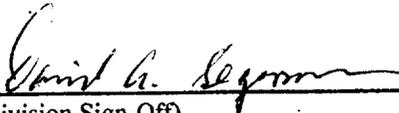
Indications for Use:

QLV-CMS provides quantitative information regarding the calculated dimensions and calculated performance characteristics of the left ventricle of the heart, imaged during angiographic x-ray procedures typically performed in cardiac cath labs. This information is suitable for use by physicians and scientists in the following applications:

1. Scientific and research studies, assessing the angiographic condition of patients and the results of device and drug therapies,
2. Review and analysis of patient angiographic imaging records, providing additional information to physicians and administrators.

(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 K993765

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)