

K993761

MEDIS *medical imaging systems, inc.*

DEC 28 1999

CMS - View
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)

Submitter : MEDIS medical imaging systems, Inc.
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Ridgefield, CT 06877, USA
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Fax : 203.438.5393
Contact Person : Douglas Orr, President
Prepared : July 30, 1999

2) Device Name : Cardiovascular Measurement System - View
Common Name : CMS - View
Device Class. Name : System, Image Processing;
Regulation Number : 21 CFR 892.2050 (90 LLZ; Class II)

3) Predicate Device(s) : RadWorks Medical Imaging Software
510(k) Number: K982862 and K962699

Description of the device:

CMS-View is a professional state-of-the-art DICOM Review Station, designed for use with Microsoft Windows operating systems (preferably, Windows NT). CMS-View facilitates the import and visualization of medical images from a range of different image sources (DICOM-CD, network, VCR, etc.) for use by trained medical personnel (technologists, cardiologists, radiologists, other physicians, etc.). CMS-View may be used either independently or in conjunction with other software products from MEDIS.

5) Intended use:

CMS-View can be used in the traditional medical image review applications, including cardiac catheterization rooms, physician offices and other locations apart from the medical clinic or provider location. There are extensive image review controls that are useful to control the viewing process to the preference of the clinical user, supporting visual inspections for further use by a trained medical person.

6) Substantial equivalence Information:

MEDIS believes the CMS-View software is substantially equivalent to the predicate device RadWorks Medical Imaging Software (K982862 / K962699) as both products employ the same technological characteristics and intended use.

Conclusion respecting safety and effectiveness:

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

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6

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Douglas F. Orr
President
Medis Medical Imaging Systems, Inc.
109 Danbury Road
Ridgefield, Connecticut 06877RE: K993761
CMS – View
Dated: July 30, 1999
Received: November 8, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

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

510(k) Number (if known): K993761

Device Name: _____

Indications For Use:

510(k) Number: K993761
Device Name: Cardiovascular Measurement system - VIEW (CMS-VIEW)

Indications for Use:

CMS-View provides a means for the playback and/or review of medical images or imaging sequences by physicians, scientists or other medical personnel. These medical images may originate from different imaging modalities (x-ray, MRI, ultrasound, nuclear, etc.) and are input to the CMS-VIEW system via industry standard formats (DICOM) or by creating a digital equivalent of a video-format (via frame-grabber). Standard image review tools are provided, including zoom, brightness and contrast controls.

The review of medical images is suitable for use by physicians and scientists in the following applications:

1. Scientific and research studies, selecting and assessing medical images that are of interest,
2. Review and analysis of patient medical images, providing physicians and administrators with convenient access and review features/capabilities.

(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 K993761

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)