K060840

MRI Cardiac Services, Inc.

510(k) Summary

APR 7 2006

Submitter:
MRI Cardiac Services, Inc.
8 West Third Street, M9
Winston-Salem, NC 27101
336-831-1908 (v)
336-727-0919 (f)

Date Prepared:
June 1, 2004

Contact Person(s):
Scott Huber, President
336-831-1908 (v)
336-727-0919 (f)

Device Trade Name: SView™

Device Common Name:
PACS / Medical Image Management Device

Classification Name:
Class II — System, Image Processing

Product Code/Regulation Number:
LLZ/892.2050

Substantially Equivalent To:
AccuView Diagnostic Imaging Workstation Software Package
(K990241)
AccuImage Diagnostics Corporation
400 Oyster Point Boulevard, Suite 114
S. San Francisco, CA 94080

Device Description:
SView™ 1.0 is a tool for 2D (two-dimensional) viewing and manipulation of DICOM compliant MR images and other DICOM-compliant images. The proposed device provides real-time image viewing, manipulation, analysis and reporting.

Indications for Use:
SView™ 1.0 is a medical image management device intended for viewing, manipulating and analyzing DICOM-compliant medical images acquired from MRI scanners and other DICOM –compliant imaging devices. SView™ 1.0 can be used for real-time image viewing, image manipulation, and analysis that aid a cardiologist or radiologist in their diagnosis. In addition, it facilitates the physician's reporting and

reviewing of patient studies.

Technological Comparison to Predicate Device:
The proposed and predicate medical image management devices are both devices that can be used for manipulation of DICOM-compliant MR images. The proposed and predicate device can be operated from a personal computer. SView™ 1.0 and a standard Windows operating system. SView is a subset of the AccuView Diagnostic Imaging Workstation features with an optional added monitor to allow a Cardiologist or Radiologist the convenience of using two monitors, one for image viewing and manipulation, and the other for reporting. SView™ 1.0 has substantially equivalent features and specifications versus the existing AccuView Diagnostic Imaging Workstation for those features and specifications the two devices have in common.

Laboratory and Clinical Testing
SView™ 1.0 is intended for use with existing MRI images for real-time image viewing, image manipulation, and analysis that aid a cardiologist or radiologist in their diagnosis. In addition it facilitates the physician's reporting and reviewing of patient studies. The SView™ medical image management device contains no image digitizers and uses only lossless compression. On this basis, MRI Cardiac Services, Inc. believes that clinical investigation is not necessary.

Extensive testing of the device will be performed by programmers, by non-programmers, quality assurance staff and by potential customers prior to commercial release.

Adverse Effects on Health:
The potential hazards are identified in the Hazard Analysis and are controlled by:

- Designing controls directed at the cause and/or
- Introducing protective measures and/or
- Warning the Users

All identified hazards are mitigated to minor level of concern.

See Summary of Safety and Effectiveness on the following page.

Conclusions:
We conclude that the subject device, SView™ 1.0 is as safe and effective as the predicate device and posses no new questions of safety and effectiveness. SView™ 1.0 performs in accordance with its intended use as well as the AccuView Diagnostic Imaging device currently on the market. MRI Cardiac Services, Inc. considers features of the SView™ 1.0 to be substantially equivalent to the subset of features in common with the AccuView. Diagnostic Imaging device (510(k)990241.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

MRI Cardiac Services, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K060840
Trade/Device Name: SView™ Version 1.0 PACS
Medical Image Management Device
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 27, 2006
Received: March 28, 2006

Dear Mr. Lehtonen:

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.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" (21 CFR 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 (301) 443-6597 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

Indications for Use

501(k) Number: K060840

Device Name: SView™ Version 1.0 PACS/Medical Image Management Device

Indications For Use:

SView™ 1.0 is a medical image management device intended for viewing, manipulating and analyzing DICOM-compliant medical images acquired from MRI scanners and other DICOM –compliant imaging devices. SView™ 1.0 can be used for real-time image viewing, manipulation and analysis that aid a cardiologist or radiologist in their diagnosis. In addition, it facilitates the physician's reporting and reviewing of patient studies.

Prescription Use X OR Over- The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060840