K103679
MAR - 3 2011

5. 510(k) Summary

5.1 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for axis PACS and HMS PACS, in accordance with 21 CFR 807 Subpart E.

5.1.1. Submitted By

Business Name:	axis Health Care, LLC 5755 Carmichael Parkway Montgomery, Alabama 36117
Contact Name:	William D. Henderson, President
Contact E-mail:	dwight.henderson@hcsinc.net
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Registration Number:	Not assigned
Small Business Decision Number:	SBD 118249
Date Prepared:	December 16, 2010

5.1.2. Device Trade Name

Proprietary Name of Device:	axis PACS
Other Proprietary Name of Device:	HMS PACS
Classification:	Picture Archiving and Communication System (PACS)
Device Classification:	Class II Medical Device
Product Code:	LLZ
21 CFR Regulation	892.2050

5.1.3. Predicate Device

Predicate Device:	e-Film Workstation with Modules
Predicate Device Manufacturer:	Merge eFilm Medical, Inc. (Merge Healthcare)
Predicate Device 510(k) Number:	K020995
Date Received:	March 28, 2002
Decision Date:	April 12, 2002
Decision:	Substantially Equivalent
Device Classification:	Class II Medical Device
Product Code:	LLZ
21 CFR Regulation	892.2050

5.1.4. Device Description

axis PACS is a Picture Archiving and Communication System (PACS) designed for the management, viewing, archiving, manipulation, and processing of DICOM 3.0 images from modalities in a diagnostic imaging setting. axis PACS consists of the axis PACS Web software application on a server and the axis PACS viewer running on client computers connecting to the server via the HTTPS protocol. axis PACS can also transfer DICOM 3.0 images over a medical imaging network, as well as export images to other applications.

5.1.5. Indications for Use

axis PACS is a software application intended to perform operations relating to acquisition, display, digital processing, review, transfer, archive, measurements, teleradiology exchange of medical images and patient demographic information. axis PACS receives digital images and data from various modalities, including but not limited to, Computed Radiography (CR), Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Fluoroscopy (RF), secondary screen captures devices, scanners, digitizers, or other imaging sources.

It is intended for use by the physician to aid diagnosis and used by medical professionals whenever they require access to medical images and patient demographic information. Users have access to a variety of measurement tools and image processing to aid them in viewing digital images.

This device may be used to archive mammography images (MG) but is not intended for primary diagnostic viewing of mammography images.

axis PACS can integrate with a health care institution's or physician's office Health Information System (HIS) or a Radiology Information System (RIS) for a fully integrated electronic patient record.

Typical users of axis PACS are trained medical professionals including radiologists, physicians, radiology technologists, and other clinicians.

5.1.6. Technological Characteristics and Substantial Equivalence

Compared to the predicate device, axis PACS has the same technological characteristics. These include operating system, functionality, conformance with voluntary standards, and presentation characteristics. Both predicate device and axis PACS can transmit images and information over a medical imaging network and to remote viewing stations.

axis PACS does not physically come in contact with a patient nor does it control any life sustaining device. A physician has ample opportunity to provide competent human intervention and interpretation of images and medical information as displayed or printed via axis PACS.

5.1.7. Performance Testing

axis PACS was tested to validate and verify that the device meets voluntary standards specified in 21 CFR 892.2050(b), with defined design and performance specifications. The results of the testing confirmed that axis PACS performed as intended and performed to substantial equivalence (SE) to the predicate device. The application is as safe and effective in the performance as a PACS as compared to the predicate device.

Testing is an integral part of axis PACS development process as outlined and supported by information provided in Section 11, 12 and 16 of this submission.

(i) Nonclinical tests:

A final non-clinical test with the predicate device was conducted November 22, 2010 at the axis Health Care office in Montgomery, AL. axis PACS was tested side-by-side with the predicate device, e-Film

Workstation with Modules version 2.1. DICOM calibration images and actual patient images were used in both systems during the comparison testing.

(ii) Clinical tests:

a.) Subjects tested

b.) Safety and Effectiveness

c.) Adverse Effects and Complications

A clinical test at Bedford Medical center in Bedford, Indiana was conducted Oct. 1-3, 2010 under the supervision of the hospital's radiologist. The facility has the predicate software and has been using it for 3+ years. The products were compared side-by-side and the results are included in:

- Attachment 19 Application Test Script axis PACS Radiologist Workstation (RW)

(Note: **Radiologist Workstation** – This term is used interchangeably within this document and supporting documents with Diagnostic Station, Diagnostic Workstation, Read Station, Diagnostic Read Workstation. All terms mean the workstation used by the radiologist to view digital images from the axis PACS archive.)

No subjects were directly included in the clinical test. All tests were indirect as DICOM images were already obtained by the modalities.

It was concluded the axis PACS is as safe and effective, performed as well as or exceeded, the predicate device, e-Film Workstation with Modules.

5.1.8. Conclusion

The axis PACS 510(k) premarket notification contains adequate information and data to enable FDA-CDRH to determine substantial equivalence (SE) to the predicate device.

- axis PACS is manufactured according to the voluntary standards, 21 CFR 892.2050(b), and in compliance with 21 CFR 820 Quality System Regulations.
- This submission contains the results of the software validation and verification along with the risk analysis. The risks have been classified as moderate level of concern and the submission provides solutions to mitigate those risks.
- axis PACS complies with 21 CFR Part 807 Subpart B associated with registration and listing.
- axis PACS complies with 21 CFR Part 801 associated with proper labeling of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Ronald W. Graham
Vice President Operations
axis Health Care, LLC
5755 Carmichael Parkway
MONTGOMERY AL 36117

MAR - 3 2011

Re: K103679
Trade/Device Name: axis PACS and HMS PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 16, 2010
Received: December 22, 2010

Dear Mr. Graham:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. FDA Indications for Use Statement

FDA Indications for Use Form

510(k) Number: K103679

Device Name: axis PACS and HMS PACS

Indications For Use:

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Prescription Use: ✓ **AND/OR** **Over-The-Counter Use:** _____

(Part 21 CFR 801 subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103679