K111319

AUG - 5 2011

Appendix A: 510(k) Summary

1. **Date of Summary:** 30 June 2011

2. **510(k) Applicant**

MedQIA
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3. **Device Overview**

Trade Name:	IBIS Explorer and Markup Software
Common Name:	Picture Archiving and Communication Systems (PACS)
Classification Name:	System, Image Processing, Radiological 21 CFR 892.2050 Product Code LLZ

4. **Predicate Device**

The predicate devices identified for the IBIS Explorer and Markup Software are as follows:

Trade Name	510(k) Submitter	510(k) Number
syngo® Dynamics	Siemens AG Medical Solutions	K053133, cleared on December 5, 2005
VISAGE® PACS/CS 6.0	Mercury Computer System, Inc	K082269, cleared to market on December 12, 2008

5. **Device Description**

The IBIS Explorer and Markup Software is a picture archival and communications system (PACS) providing researchers, radiologists or health care professionals with the tools to accept, display, store, archive and manipulate digital medical images. The IBIS Explorer stores, archives and displays digital medical images, while the Markup Software allows for measurements of specified regions and report generation. Digital images supported by the software include but are not limited to bone scans, chest

radiograph (x-ray), ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI).

The System is to be used by trained professionals who are responsible for the correct and accurate use of medical images and the subsequent diagnosis. In a typical clinical environment, the system would be used by a trained technician and radiologist.

The software is installed on an off-the-shelf PC computer system. It is intended to be used with uncompressed digital images that are saved in DICOM format.

6. Intended Use

IBIS Explorer and Markup Software is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.

Besides general image interpretation and processing tools, IBIS provides specific tool sets for several clinical applications, including:

- Oncology, including lesion marking and analysis
- Anatomic structure marking, volume measurement and analysis

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for image diagnosis.

Only uncompressed or non-lossy compressed images must be used for image diagnosis in mammography.

7. Comparison to Predicate Device

The IBIS Explorer and Markup Software is substantially equivalent to the predicate devices. The software has the same intended use and similar technological characteristics, which do not raise any new questions of safety or effectiveness.

8. Performance Data

Comprehensive design verification and validation (V&V) was performed to ensure that the IBIS Explorer and Markup Software meets its intended use, customer requirements and software requirements. The V&V testing included functional verification of all software requirements and comprehensive validation of user requirements. Testing also included verifying the accuracy of the measurements of the Markup Software against the Visage PACS/CS predicate device. Testing was conducted using various DICOM image modalities from different scanners (GE, Toshiba, Philips and Siemens). All testing was conducted at MedQIA and, therefore, represents a typical user site. Traceability of the test cases to the requirements ensures that all requirements have been verified and validated. Testing confirmed that no anomalies affect the quality or clinical usability of the system.

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

MedQIA
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG - 5 2011

Re: K111319
Trade/Device Name: IBIS Explorer and Markup System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 5, 2011
Received: July 6, 2011

Dear Mr. Job:

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 S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K_____

Device Name:

Indications for Use:

IBIS Explorer and Markup Software is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-CounterUse _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111319