K101342

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
March 7, 2010

AUG 2 0 2010

Submitter's Information: 21 CFR 807.92(a)(1)

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	OsiriX MD™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K063470
Regulation Number	892.2050
Device Name	aycan Workstation OsiriX
Applicant	aycan Digitalsysteme GmbH Innere Aumuehlstrasse 5 97076 Wurerzburg, Germany
Classification Product Code	LLZ
Decision Date	01/06/2007
Classification Advisory Committee	Radiology

Device Description: 21 CFR 807 92(a)(4)

The OsiriX MD software is an interactive image display and navigation program that was designed medical imaging modalities. It supports all types of images generated by variety of imaging equipment and scanners available today. It supports the DICOM standard for image communication as well as a variety of other image formats used in academic and research community. OsiriX MD is tailored for large sets of multidimensional and multi-modality images such as combined PET-CT studies that require three dimensional image fusion and volume rendering. The software is developed on a Macintosh platform taking advantage of the underlying UNIX kernel of the Mac OS X operating optimized 3D graphic capabilities of Open GL graphic standard that is widely used for computer games and animations and is highly optimized on the Macintosh platform for taking advantage of any hardware graphic accelerator boards that would be available. The software was developed in Objective-C in Apple Cocoa development environment. In the design of the software a special attention was given to adapt the user

interface to navigating through large sets of image data. The graphical user interface also uses the Macintosh interface. Users can change and customize the software by adding and removing tools and items from the program toolbar and menu bars. This allows for adapting the software for number of functions and avoiding the users to be overwhelmed by an excessive number of unnecessary tools and functions that are not always needed.

Indications for Use: 21 CFR 807 92(a)(5)

OsiriX MD™ is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

Technological Characteristics: 21 CFR 807 92(a)(6)

OsiriX MD is a software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

OsiriX MD software requires Mac OS X version 10.5 (Leopard) or higher. Although the software will work on any Macintosh platform, performance of some of the advanced image rendering tools and volume rendering of large image sets it is recommended to use high end machines equipped with Intel processors (the faster the better). OsiriX MD also takes advantage of multiprocessor and multi-core machines to speed up rendering functions. Memory requirement will depend on the type and size of image sets you will be working with.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for OsiriX MD contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, intended use, and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. OsiriX MD is substantially equivalent with respect to safety and effectiveness to the predicate 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

Pixmeo Sarl
% Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Inc.
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AUG 2 0 2010

Re: K101342
Trade/Device Name: OsiriX MD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 21, 2010
Received: July 22, 2010

Dear Mr. Devine:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101342

Indications for Use

510(k) Number (if known):

Device Name:

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 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 In Vitro Diagnostic Devices (OIVD)

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

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