K063470

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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:

November 8, 2000

JAN - 5 2007

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

Mr. Stephan Lange
aycan Digitalsysteme GmbH
Innere Aumuehlstrasse 5
97076 Wurerzburg, Germany

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

Trade Name:	aycan Workstation OsiriX
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ

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

FDA has classified the predicate device (K062488) as Class II, CFR 892.2050, LLZ. It is our understanding that *aycan Workstation OsiriX* device falls under the same classification as the predicate device. Predicate device details are as follows:

Device Classification Name	system, image processing, radiological
510(k) Number	K062488
Regulation Number	892.2050
Device Name	IQ-SYSTEM PACS SYSTEM
Applicant	IMAGE INFORMATION SYSTEMS, LTD.
Classification Product Code	LLZ
Decision Date	09/19/2006
Classification Advisory Committee	Radiology

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

The *aycan Workstation OsiriX* provides services for review and post processing of diagnostic medical images and information. It conforms to the DICOM 3.0 standard to allow the sharing of medical information with other digital imaging systems. *aycan workstation OsiriX* runs on Apple Mac OSX systems and provides high performance review, navigation and post processing functionality for multidimensional and multimodality images.

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

aycan Workstation OsiriX 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 clinical application.

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

aycan Workstation OsiriX is a software device that handles and manipulates digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Testing:

As required by the risk analysis, designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The system passed all testing criteria.

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

The 510(k) Pre-Market Notification for *aycan Workstation OsiriX* contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Acyan Digitalsysteme GmbH
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

JAN 0 5 2007

Re: K063470
Trade/Device Name: aycan Workstation OsiriX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 13, 2006
Received: November 21, 2006

Dear Mr. Alletto:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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 Form)

510(k) Number: K063470

Device Name: aycan Workstation OsiriX

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063470