K103546
P. 1 of 2

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 24, 2010

MAR 17 2011

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

Mr. Matthias Broenner
aycan Digitalsysteme GmbH
Innere Aumuehlstr. 5
97076 Wurerzburg
Germany

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

Trade Name:	aycan workstation OsiriX PRO
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 (K063470) 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:	K063470
Regulation Number:	892.2050
Device Name:	aycan workstation OsiriX
Applicant:	aycan Digitalsysteme GmbH Innere Aumuehlstr. 5 97076 Wuerzburg Germany
Classification Product Code:	LLZ
Decision Date:	01/05/2007
Classification Advisory Committee:	Radiology

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

The *aycan workstation OsiriX PRO* 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*

PRO 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 PRO 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 PRO 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 PRO* 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 "Moderate".

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. Matthias Broenner
Quality and Regulations Manager
aycan Digitalsysteme GmbH
Innere Aumuehlstr. 5
97076 Wuerzburg
GERMANY

MAR 17 2011

Re: K103546
Trade/Device Name: aycan workstation OsiriX PRO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 24, 2010
Received: December 2, 2010

Dear Mr. Broenner:

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, 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 Form

510(k) Number:

Device Name: aycan workstation OsiriX PRO

Indications for Use:

aycan workstation OsiriX PRO 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.

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)

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

510K K103546