aycan
PACS for People

510(k) Summary of Safety and Effectiveness

SEP 12 2012

The following information is in conformance with 21 CFR 807.92.

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

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Contact Person:	Mr. Matthias Broenner
Date Prepared:	July 23th, 2012

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

Trade Name:	aycan mobile
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Regulation Number:	21 CFR 892.2050

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

FDA has classified the predicate device (K103785) as Class II, CFR 892.2050, LLZ. It is our understanding that *aycan mobile* 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:	K103785
Regulation Number:	892.2050
Device Name:	MOBILE MIM
Applicant:	MIM SOFTWARE INC. 25200 Chagrin Blvd. Suite 200 Cleveland, OH 44122
Classification Product Code:	LLZ
Decision Date:	02/04/2011
Classification Advisory Committee:	Radiology

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

aycan mobile is an App for the Apple iPad. It can be used for receiving and visualization of medical images.

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

"The *aycan mobile* software program is used to display medical images for diagnosis from CT and MRI modalities only.

aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography."

The Indications for Use of aycan mobile are a subset of the Indications for Use of the predicate device. The predicate device additionally covers registration and fusion of images and it includes the handling of SPECT and PET images. See also the Device Comparison Table below.

The reduction of the Indications for Use (compared to the predicate device) doesn't negatively affect the safety and effectiveness of the devices when used as labeled.

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

aycan mobile is a software for a mobile device (Apple iPad) that receives and visualizes 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.

Device Comparison Table between new device and predicate:

Topic	aycan mobile	MOBILE MIM
Intended Use / Indications for Use	The aycan mobile software program is used to display medical images for diagnosis from CT and MRI modalities only. aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MM. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	No	Yes
Standardized Uptake Value (SUV)	No	Yes
Distance Calculation	Yes	Yes
Window / Level	Yes	Yes
Zoom, Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	Yes
Operating Platform	Apple (R) iOS	Apple (R) iOS
Hardware Requirements	Apple (R) iPad	Apple (R) iOS handheld devices

The comparison table shows that – besides a reduction of functionality regarding the application on SPECT and PET images – both Apps are substantially equivalent.

Regarding the hardware aycan mobile is limited to iPad devices compared to MOBILE MIM which can be used on the wider range of all Apple (R) iOS handheld devices.

The differences at the Indications for Use Statement are also based on the fact that MOBILE MIM handles SPECT and PET images additionally.

All these facts provide evidence to facilitate the substantial equivalence determination between aycan mobile and the predicate device, MOBILE MIM (K103785).

Performance Data from nonclinical Testing: 21 CFR 807 92(b)(1)

Designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The system passed all testing criteria.

Extensive performance tests had been conducted regarding the display and other technical aspects. Display tests leveraged capabilities regarding IEC 62563-1 and TG18 guideline. All tests had been passed successfully.

Performance Data from clinical Testing: 21 CFR 807 92(b)(2)

Furthermore a series of studies had been performed by qualified radiologists reading different CT and MRI studies under different environmental lightning conditions. The capability of aycan mobile as a device for diagnostic reading – when used within the indications for use – was confirmed by the results of these studies.

All radiologists came to the conclusion that the devices is safe and effective when used within its defined Intended Use.

Conclusion: 21 CFR 807 92(b)(3)

According to all evidence collected, we come to the conclusion, that aycan mobile is substantially equivalent to the predicate device and it is safe and effective, when used as labeled.

The 510(k) Pre-Market Notification for *aycan mobile* contains adequate information and data to enable FDA-CDRH to determine substantial equivalence 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

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Quality and Regulations Manger
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GERMANY

SEP 12 2012

Re: K122260
Trade/Device Name: aycan mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 23, 2012
Received: July 27, 2012

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.

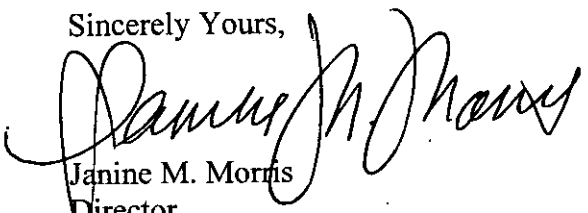
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
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: K122260

Device Name: aycan mobile

Indications for Use:

The aycan mobile software program is used to display medical images for diagnosis from CT and MRI modalities only.

aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Prescription Use _X___ 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)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510k K122260