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K103785

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510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Submitter:

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Date Summary Prepared: Jan 26, 2011

Device Name

Trade Name: Mobile MIM
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Device

K062163 MIMviewer 1.0 MIM Software Inc. (formerly MIMvista Corp.)

Intended Use / Indications for Use

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 MRI.

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.



Device Description

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 MRI.

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.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Device Comparison Table between new device and predicate:

ITEM	Mobile MIM	MIMviewer
Intended Use / Indications For Use	<p>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 MRI.</p> <p>Mobile MIM provides wireless and portable access</p>	<p>MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities.</p> <p>The MIMviewer software</p>

ITEM	Mobile MIM	MIMviewer
	<p>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.</p> <p>This device is not to be used for mammography.</p>	<p>program is used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.</p>
<p>Receive, Store, Retrieve, Display, and Process Digital Medical Images</p>	<p>Yes</p>	<p>Yes</p>
<p>Display of Clinical Patient Data When No Access to a Workstation</p>	<p>Yes</p>	<p>Yes</p>
<p>Image Fusion</p>	<p>Yes</p>	<p>Yes</p>
<p>Multi-Planar Reconstruction (MPR)</p>	<p>Yes</p>	<p>Yes</p>
<p>Maximum Intensity Projection (MIP)</p>	<p>Yes</p>	<p>Yes</p>
<p>Standardized Uptake Value (SUV)</p>	<p>Yes</p>	<p>Yes</p>
<p>Distance Measurements</p>	<p>Yes</p>	<p>Yes</p>

ITEM	Mobile MIM	MIMviewer
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	SPECT, PET, CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	No
Operating Platform	Apple® iOS	Windows® 2000/XP MacOS X® 10.4+ Linux®
Hardware Requirements	Apple® iOS handheld devices	Pentium® 4+ G4+

Substantial Equivalence

The comparison chart above provides evidence to facilitate the substantial equivalence determination between Mobile MIM and our chosen predicate device, MIMviewer (K062163)

The differences in the Indication Statements between Mobile MIM and MIMviewer describe specific restrictions on how Mobile MIM is to be used, given the hardware and portability differences between these two devices. Mobile MIM adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography.



The technological characteristics between Mobile MIM and MIMviewer are different, as the software operates on different hardware. These differences are addressed through the labeling and additional software features of Mobile MIM.

Performance Data

MIM Software Inc. has conducted display performance testing using Mobile MIM software on various portable devices, both prior to and after utilizing the application's calibration procedure. Testing measured contrast response and evaluated test patterns for luminosity, resolution, and noise according to IEC 62563-1 and TG18 guidelines. All testing passed requirements following the Mobile MIM's calibration procedure.

MIM Software Inc. also performed multiple studies with qualified radiologists using a variety of modalities, specifically MRI, CT, SPECT, and PET, under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

Furthermore, MIM Software Inc. has conducted verification, validation, and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM provides a diagnostic viewer of medical images substantially equivalent to the MIMviewer software, with portable device characteristics and functionality.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K103785
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2010
Received: December 27, 2010

Dear Ms. Hanigan:

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 Pastel, ScD.
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): TBD K103785

Device Name: Mobile MIM

Indications for Use:

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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)

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


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

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