DEC - 2 2011

510(k) Summary of Safety and Effectiveness

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

Submitter:

MIM Software Inc.
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Contact Person: Lynn Hanigan

Date Summary Prepared: Sept 30, 2011

Device Name

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

Predicate Device

K103785	Mobile MIM	MIM Software Inc.
K042956	Vision	Varian Medical System

Intended Use / Indications for Use

The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound.

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

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

Mobile MIM (RT) extends the Mobile MIM software application previous cleared under K103785. In addition to SPECT, PET, CT, MRI modalities, Mobile MIM can be used for the viewing and/or display for diagnosis of X-ray and Ultrasound medical images.

It also provides functionality for the review of medical images, contours, DVH, and isodose curves from radiation treatment plans. In addition, Mobile MIM (RT) will allow permitted users the ability to approve reviewed radiation treatment plans.

Substantial Equivalence

Mobile MIM is substantially equivalent to Mobile MIM software (K103785) and portions of the Vision product (K042956). It extends Mobile MIM functionality by adding 2 additional image modalities to its indication and having the capability to serve as a mobile reviewing device for radiation treatment plans.

Performance Data

MIM Software Inc. has performed multiple studies with qualified radiologists, dosimetrists and radiation oncologists. Radiologists tested Mobile MIM by evaluating the image quality of the two additional modalities of X-ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

MIM Software also orchestrated radiation therapy plan review tests evaluating multiple areas of treatments by trained medical professionals using plan data from 3 major vendors, and using both smaller format (iPhone and/or iPod touch) and larger format (iPad) devices. The results indicated the display quality for of isodose curves, DVH graphs, and contours was of acceptable quality for review and approval of radiation therapy plans, and were equivalent to those viewed on a full workstation.

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.

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Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM (RT) provides a safe and effective diagnostic viewer of the following medical imaging modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. It also is safe and effective in that it is substantially equivalent to the radiation treatment plan review functionality of Vision (K042956), allowing for portable device characteristics and accessibility when there is no access to a full workstation.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Ms. Lynn Hanigan
Quality Manager
MIM Software, Inc.
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DEC - 2 2011

Re: K112930
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ & MUJ
Dated: September 30, 2011
Received: October 3, 2011

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 S. Pastel

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

510(k) Number (if known): TBD K112930

Device Name: Mobile MIM

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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

510(k) K112930