



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

MIM Software Inc.
% Ms. Lynn Hanigan
Quality Assurance Director
25800 Science Park Drive, Suite 180
CLEVELAND OH 44122

April 25, 2016

Re: K151913
Trade/Device Name: MIM-Thin Client (mobile)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 12, 2016
Received: April 13, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151913

Device Name

MIM - Thin Client (mobile)

Indications for Use (Describe)

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

- Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.
- Create, display and print reports from medical images.
- Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.
- Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.
- Localization and definition of objects such as tumors and normal tissues in medical images.
- Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.
- Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.
- Planning and evaluation of permanent implant brachytherapy procedures.

When used for diagnostic purposes, the mobile thin client is not intended to replace a full workstation and should only be used when there is no access to a workstation.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.



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510(k) Summary of Safety and Effectiveness
(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25800 Science Park Drive – Suite 180
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: 4/21/2016

Device Name

Trade Name: MIM – *Thin Client (mobile)*
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K103576	MIM	MIM Software Inc.
K112930	Mobile MIM	MIM Software Inc.

Intended Use

MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists.

MIM is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.

MIM provides the user with the means to display, register and fuse medical images from multiple modalities. Additionally, it evaluates cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.

The Region of Interest (ROI) feature reduces the time necessary for the user to define objects in medical image volumes by providing an initial definition of object contours. The objects include, but are not limited to, tumors and normal tissues.



MIM provides tools to quickly create, transform, and modify contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems and archiving contours for patient follow-up and management.

MIM aids in the assessment of PET/SPECT brain scans. It provides automated quantitative and statistical analysis by automatically registering PET/SPECT brain scans to a standard template and comparing intensity values to a reference database or to other PET/SPECT scans on a voxel by voxel basis, within stereotactic surface projections or standardized regions of interest.

MIM allows the dose distribution of an implant to be individually shaped for each patient and is a general purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using permanent implants of various radioisotopes.

Indications for Use

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

- Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.
- Create, display and print reports from medical images.
- Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.
- Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.
- Localization and definition of objects such as tumors and normal tissues in medical images.
- Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.
- Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.
- Planning and evaluation of permanent implant brachytherapy procedures.

When used for diagnostic purposes, the mobile thin client is not intended to replace a full workstation and should only be used when there is no access to a workstation.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.



Device Description

MIM – *Thin Client (mobile)* is a software package designed for use in diagnostic imaging and oncology. It is a stand-alone package, which operates on both Windows and Mac computer systems and can be configured as a server for display and advanced visualization of medical image data on remote workstations or high-resolution mobile devices. Off-the-shelf software, such as Citrix, will provide connectivity between the MIM workstation, when acting as a server, and the remote display.

MIM aids the efficiency of medical professionals by providing various tools for display, registration and fusion of medical images from multiple modalities, to quickly create, transform, and modify contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

MIM functions as a medical image and information management system intended to receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images. It also functions as a general-purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using permanent implants of various radioisotopes.

Substantial Equivalence

The predicates of MIM software (K103576) and Mobile MIM (K112930) were chosen for the following reasons:

- MIM – *Thin Client (mobile)* and MIM software (K103576) have the same intended use.
- MIM – *Thin Client (mobile)* and MIM software (K103576) have the same indications for use except for one caveat. “When used for diagnostic purposes, the mobile thin client is not intended to replace a full workstation and should only be used when there is no access to a workstation.”
- MIM – *Thin Client (mobile)* does differ in technological characteristics. Off-the-shelf software, such as Citrix, can provide connectivity between the MIM workstation, when acting as a server, for display and advanced visualization of medical image data on portable devices. This technological difference, however, does not affect safety or effectiveness.
- The additions of the calibration and verification tools that are similar to those used in Mobile MIM (K112930) ensure the safe and effective use of MIM – *Thin Client (mobile)*.



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Performance Data

Testing with MIM – *Thin client (mobile)* was performed by board certified radiologists. Results of these studies affirm the diagnostic image viewing capabilities of MIM – *Thin Client (mobile)* when used as indicated. The following devices were validated for diagnostic reading:

Apple iPad - A1458 - iOS 7
Kindle Fire HDX 8.9 - GU045RW - Fire OS 4.5
Samsung Galaxy NotePRO - SM-P905V - Android 4.4.2
Windows Surface - 1516 - Windows RT

Furthermore, MIM Software Inc. has conducted performance and functional testing on the MIM – *Thin Client (mobile)* software. In all cases, the software passed its performance requirements and met specifications.