FEB 18 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: Dec 2, 2010

Device Name

Trade Name: MIM 5.2 (Brachy)
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K071964	MIM 4.1 (SEASTAR)	MIM Software Inc. (formerly MIMvista Corp.)
K992762	Brachyvision 6.0	Varian Medical Systems
K030534	VariSeed 7.1	Varian Medical Systems

Intended Use

MIM 5.2 software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists.

MIM 5.2 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 5.2 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 5.2 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 5.2 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 5.2 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 5.2 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 5.2 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.

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- 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.

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 5.2 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. MIM 5.2 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 5.2 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. MIM 5.2 is an expansion of MIM 4.1 (SEASTAR) software, which was granted marketing clearance to MIM Software Inc. (formerly MIMvista Corp.) on September 26, 2007 under 510(k) Accession Number 071964 with the following additional features and capabilities allowing it to become 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:

- allows for structure contouring on a patient scan and specifying any implant vector for seed implant. MIM 5.2 will re-slice and display the scan orthogonal to the specified vector.

- allows for automatic generation of 3D display of patient data and contours.

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- allows user to select an implant template from a template database. The template grid will be displayed upon patient scan. The user is able to align the template to the desired location.

- allows user to specify the type of seed from a seed database. The user is able to manually place seeds either at locations specified by a template grid or at arbitrary locations within the scan. Based on the type and location of the seeds, MIM 5.2 will update the dose volume in real time to reflect current dose coverage. MIM 5.2 allows the user to change isodose line settings.

- allows saving the treatment plan. The saved plan can be loaded for evaluation and modification.

- allows generation of seed planning report which contains information of template type, seed type, seed locations, needle configuration, screen captures, 3D displays, and re-slicing vector. The report can be exported as an electronic file (e.g. PDF or DICOM SR) and easily transferred to seed vendor.

Substantial Equivalence

MIM 5.2 is substantially equivalent to a combination of the predicate devices MIM 4.1 (SEASTAR) - K071964, Brachyvision 6.0 - K992762, and VariSeed 7.1 - K030534.

MIM 5.2 extends the MIM 4.1 software application by adding functionality to act as a general purpose brachytherapy planning system providing prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using permanent implants of various radioisotopes. This functionality is substantially equivalent to Brachyvision 6.0 and VariSeed 7.1.

Performance Data

MIM Software Inc. has conducted performance and functional testing on the MIM 5.2 software. In all cases, the software passed its performance requirements and met specifications.

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Silver Spring, MD 20993-0002

Ms. Lynn Hanigan
Quality Manager
MIM Software, Inc.
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FEB 18 2011

Re: K103576
Trade/Device Name: MIM 5.2 (Brachy)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 8, 2011
Received: February 9, 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 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

Device Name: MIM 5.2 (Brachy)

Indications for Use:

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- Localization and definition of objects such as tumors and normal tissues in medical images.
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) K103576

- Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.

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