K071964

MIMvista

510(k) Summary of Safety and Effectiveness

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

SEP 26 2007

Submitter:

MIMvista Corp.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

Phone: 216-896-9798
Fax: 216-896-9796

Contact Person: Peter Simmelink

Date Summary Prepared: July 13, 2007

Device Name

Trade Name: MIM 4.1 (SEASTAR)
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K060816	MIM™ 4.0	MIMvista Corp.
K061006	IKOEngelo™	IKOEtech, LLC.
K043415	Centricity™ PACS System	GE Medical Systems Information Technologies

Intended Use

MIM 4.1 (SEASTAR) software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists.

MIM 4.1 (SEASTAR) 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 4.1 (SEASTAR) 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 4.1 (SEASTAR) 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 4.1 (SEASTAR) also 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.

Indications for Use

MIM 4.1 (SEASTAR) 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 4.1 (SEASTAR) 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

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 4.1 (SEASTAR) is a software package designed for use in diagnostic imaging. It is a stand-alone software package which operates on Windows 2000/XP. Its intended function and use is to provide medical professionals with the means to display, register and fuse medical images from multiple modalities including DICOM PET, ECAT PET, SPECT, CT and MRI. Additionally, it evaluates cardiac left ventricular function and perfusion including left ventricular end-diastolic volume, end-systolic volume, ejection fraction, volumetric curve, Region of Interest (ROI) contouring, and quantitative/statistical analysis of PET/SPECT brain scans through nonlinear registration to template space.

MIM 4.1 (SEASTAR) aids the efficiency of medical professionals in the creation of contours defining, but not limited to, normal and tumor tissues. The software automatically generates contours using a deformable registration technique which registers pre-contoured patients to target patients. Registrations are either between a serial pair of intra-patient volumes or between a pre-existing atlas of contoured patients and a patient volume. This process facilitates contour creation or re-contouring for adaptive therapy.

MIM 4.1 (SEASTAR) additionally 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. The system has the ability to send data to DICOM-ready devices for image storage, retrieval and transmission.

Substantial Equivalence

MIM 4.1 (SEASTAR) is substantially equivalent to the following: MIM™ 4.0 (NEURO) software (K060816), IKOEngelo™ software (K061006) and Centricity™ PACS System software (K043415).

Performance Data

MIMvista has conducted performance and functional testing on the MIM 4.1 (SEASTAR) software. In all cases, the software passed its performance requirements and met specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 26 2007

Mr. Peter Simmelink
Chief Operating Officer
MIMvista Corporation
25200 Chagrin Blvd., Suite 200
CLEVELAND OH 44122

Re: K071964
Trade/Device Name: MIM 4.1 (SEASTAR)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 13, 2007
Received: July 16, 2007

Dear Mr. Simmelink:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071964

Device Name: MIM

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Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071964

(Posted November 13, 2003)