K060816

510(k) Summary of Safety and Effectiveness

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

Submitter:

MIMvista Corp.
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Contact Person: Peter Simmelink

Date Summary Prepared: March 24, 2006

Device Name

Trade Name: MIM 4.0 (NEURO)
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K052379	MIM® 3.5	MIMvista Corp.
K041022	NeuroQ™	Syntermed, Inc.
K042863	Scenium™	Siemens Molecular Imaging Ltd.
K010726	Mirage™	Segami Corp.

Intended Use

MIM 4.0 (NEURO) is a software package that provides the physician 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 physician 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 organs.

MIM 4.0 (NEURO) also aids the physician 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 within standardized regions of interest.

K060616

Device Description

MIM 4.0 (NEURO) is a software package designed for use in diagnostic imaging. It is a standalone software package which operates on Windows 2000/XP. Its intended function and use is to provide the physician 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.

Substantial Equivalence

MIM® 4.0 (NEURO) is substantially equivalent to; MIM® 3.5 (CIRCA) software (K052379), NeuroQ™ software (K041022), Scenium™ software (K042863) and Mirage™ (NeuroGam™, NeuroMatch™) Software (K010726).

Performance Data

MIMvista has conducted performance and functional testing on the MIM 4.0 (NEURO) software. In all cases, the software passed its' performance requirements and met specifications.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 16 2006

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

Re: K060816
Trade/Device Name: MIM 4.0 (NEURO)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 24, 2006
Received: March 27, 2006

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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): ~~TBD~~ K060816

Device Name: MIM

Indications for Use:

The MIM software program should be used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIM assists in definition of structures in medical images including tumors, organs, and cardiac left ventricular cavity. MIM aids in the assessment of PET/SPECT brain scans by providing quantitative and statistical comparisons to other registered PET/SPECT brain scans.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060814

(Posted November 13, 2003)