SEP - 8 2005

510(k) Summary

K052305

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h) and as described in 21 CFR 807.92.

Submitter (510k Owner)	Siemens Medical Solutions USA, Inc. Computer Aided Diagnosis & Therapy Group 51 Valley Stream Parkway Malvern, PA 19355 Tel: (610) 448-4530 Fax: (610) 219-1419		
Contact	Barry V. Ashar Makromed, Inc. 45 Stiles Road Salem, NH 03079 Tel: (603) 890-3311 Fax: (603) 890-3322 bashar@makromed.com		
Date of Preparation	July 7, 2005		
Device Trade Name	MRI Soft Tissue Motion Correction Software		
Device Common Name	MRI Image Processing Software		
Classification Name	Class II: Picture Archiving and Communications System (21 CFR 892.2050) Product Code LLZ: Image Processing System		
Substantial Equivalence	CADstream v.4.0	K043216	Confirma, Inc.
	Fusion 7D	K020546	Mirada Solutions Ltd. (Now Siemens Medical Solutions, Inc.)
	Leonardo	K040970	Siemens Medical Solutions USA, Inc.

Device Description

MRI Soft Tissue Motion Correction Software VA10A provides the functionality to correct soft tissue motion of the MRI image volume between scan times. It supports the correction (registration) of one or more volumes relative to an initially supplied reference volume.

The product reduces image deformation and displacement in soft tissues shape and location that may occur due to patient motion in between acquisitions of serial MRI images. Correction of within imaging plane and across- plane motion is supported.

The software corrects for inter-volume rigid displacement and non-rigid deformation between acquired MRI images. This reduces motion-related artifacts in post-processing techniques that use the corrected images as input, for example subtraction images, subtraction volume MIPs, parametric maps and mean-curve analysis.

MRI Soft Tissue Motion Correction is a plug-in module for Numaris VA21A clinical workstation (K020991) or equivalent, Leonardo 2004 (K040970) or equivalent and MammoReport Plus (K042868) or equivalent. The visualization application invokes the motion correction device, receives and stores the corrected volumes, and displays the results to the user.

MRI Soft Tissue Motion Correction provides both a high quality and a high-speed operational mode. The high-speed mode is optimized for speed, while the high-quality mode is recommended for cases having moderate to large amounts of patient motion between acquisitions and takes longer to complete.

Intended Use

The MRI Soft Tissue Motion Correction Software is an adjunctive tool to assist radiologists in interpreting magnetic resonance imaging (MRI) studies. The software is intended to be used in dynamic MRI examinations that consist of multiple image volumes where patient motion may have occurred between serial acquisitions.

The MRI Soft Tissue Motion Correction Software performs automatic 2D and/or 3D flexible registration of soft tissue. The registration process enables the correction of motion occuring both within-plane and across planes (3D). By aligning corresponding voxels, the software reduces the impact of patient motion in post-processing techniques including difference (subtraction) images, parametric displays, subtraction volume MIPs and mean-curve analysis.

Patient management decisions should not be made solely on the basis of motion corrected images and should always include review of uncorrected images.

Comparison with Predicate Devices

Automatic flexible non-rigid 3D registration of serial patient MRI acquisitions to minimize the impact of patient motion, the primary feature of VA10A software, has been given 510(k) clearance in CADstream v. 4.0 (K043216, Confirma, Inc.). Similar to CADstream, MRI Soft Tissue Motion Correction VA10A software is designed to analyze MRI studies and uses flexible non-rigid registration in 3D.

Automatic flexible non-rigid as well as rigid registration of pairs of anatomical volumetric (MRI-MRI) images to help the clinician obtain better image visualization has been given 510(k) clearance in Fusion7D (K020546, Mirada Solutions, now Siemens Medical Solutions -- CTI Mirada). MRI Soft Tissue Motion Correction also performs non-rigid deformation on MRI image pairs.

Leonardo 2004 (K040970, Siemens Medical) has already been given 510(k) clearance for providing a host of MRI image processing features. The MRI Soft Tissue Motion Correction VA10A software is a plug-in module to it and adds one specific functionality to it – motion correction for soft tissue images. All other features remain unchanged.

Test Summary

The following quality assurance measures were applied to the development of the MRI Soft Tissue Motion Correction Software VA10A in accordance with internal procedures:

Risk Analysis
Requirements Reviews
Design Reviews
Integration testing (System verification)
Final acceptance testing (Validation)
Performance testing on clinical data sets (Validation)

Conclusion

The MRI Soft Tissue Motion Correction Software VA10A is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Siemens Medical Solutions USA, Inc.
% Ms. Laura Danielson
Program Manager, Responsible
Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K052305
Trade/Device Name: MRI Soft Tissue Motion Correction Software VA10A
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Product Code: LLZ
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Product Code: LNH
Regulatory Class: II
Dated: August 19, 2005
Received: August 24, 2005

Dear Ms. Danielson:

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): K052305

Device Name: MRI Soft Tissue Motion Correction Software VA10A

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)

(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 K052305