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CorTechs

JUL 12 2002

CorTechs Labs, Inc.
6 Thirteenth Street
Charlestown, MA 02129

Abbreviated 510(k) Summary

Submitter: CorTechs Labs, Inc.

Address: 6 Thirteenth, Charlestown, MA 02129

Phone number: 617 241-9588

Fax number: 617 241-9620

Contact person: Jeffrey M. Anderson, Ph.D.

Date prepared: April 12, 2002

Device Trade name: AutoAlign

Device Common name: The AutoAlign system

Device Classification name: 21 CFR 892.2050 Picture archiving and communications system.

Product Code: LLZ

Classification Panel: Radiology

Substantially Equivalent To:

Syngo Multimodality Workstation	**Advantage Windows Fusion**
(K010938) Siemens Medical Systems, Inc. 186 Wood Avenue South Iselin, NJ 08830	(K983256) GE Medical Systems P.O. Box 414, W-709 Milwaukee, WI 53201

Intended use: AutoAlign software is intended to provide an output registration matrix that may be utilized to align an MRI brain scan to a known and consistent 3-dimensional (3-D) atlas of the human brain. AutoAlign software will be marketed as a software device that can provide improvements to the manual processes of MRI brain image registration.

Device Description: The device (software) operates by comparing a subjects' brain MR localizer images to a preexisting atlas of the human brain. The software then calculates a set of coordinates that can be used to align subsequent MRI images to the atlas. The accuracy of the alignment is measured and then programmatically reported. AutoAlign is a software device that provides the following features:

- Imports MRI brain images
- Calculates and then outputs an optimized 3-D registration matrix that permits alignment of the brain, regardless of the actual physical position of the subject's head in the image. For instance, in the test alignment:
    - **in the sagittal image,** the intra-hemispheric plane is at the center slice of the MRI volume so the anterior & posterior commeasures (ac-pc line) are visible on that slice.
    - **in the axial image,** the intra-hemispheric plane is parallel to the Y axis.
    - **in the coronal image,** the intra-hemispheric plane is parallel to the Y axis.
- It can provide consistent scan/rescan alignment between separate scanning sessions within boundaries established and documented in Product Labeling Instructions.
- This software can be utilized by a MRI scanner original equipment manufacturer (OEM) to improve the workflow and automation of MRI brain study acquisitions.
- AutoAlign does not alter or otherwise modify the initial MR localizer image in any way
- The AutoAlign system does not have any adverse affects on health. This tool operates as a stand-alone software device, receives the MR scout localizer as input and outputs an optional registration prescription. AutoAlign does not alter or otherwise modify the initial MR localizer image in any way, and Labeling stipulates a review of the output registration by a trained MR operator.

Software Development: CorTechs follows generally accepted good practices and FDA's good manufacturing practices (GMP)'s in its design and software development processes. Final Verification and Validation of the software has not been completed. CorTechs will notify the FDA in writing upon completion of these activities and the company will not make this product available for commercial distribution until this has occurred.

Performance Testing: AutoAlign will successfully complete testing as detailed in the Clinical Performance Summary.

510(k) Number: None currently exists.

Device Name: AutoAlign

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Jeffrey M. Anderson, Ph.D.
Vice President of Product Development
CorTechs Labs, Inc.
6 Thirteenth Street
CHARLESTOWN MA 02129

Re: K021191
Trade/Device Name: AutoAlign
Registration of MRI brain images
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 12, 2002
Received: April 15, 2002

Dear Dr. Anderson:

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 (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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

K021191

Indications for Use:

To be utilized for the registration of brain images for MRI.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021191