K092954

5 510(k) Summary

NOV - 6 2009

This 510(k) summary is submitted as part of the PreMarket Notification in accordance with the requirements of SMDA 1990, 21 CFR 807.87(h), and 21 CFR 807.92.

1. Date Prepared	September 22, 2009
2. 510(k) Submitter	Merge CAD Inc 11040 Main Street, Suite 100 Bellevue, WA 98004 Phone: 425-691-1400 Fax: 425-691-1599
3. 510(k) Contact Person	Brent Lewis, Director Regulatory Affairs and Quality Assurance Email: brentlewis@merge.com Phone: 206-455-5398 Fax: 425-691-1599
4. Device Common Name	Image Processing System
5. Device Trade Name	CADstream Version 5
6. Classification Regulation	21 CFR 892.2050
7. Class	2
8. Panel	Radiology Panel
9. Product Code	LLZ

10. Comparison with Legally Marketed Devices

CADstream version 5 has been modified to add capability and user interface changes for calculation and presentation of apparent diffusion coefficient (ADC) maps and values, as is common in MRI imaging systems for general MRI studies. This modification is consistent with the previously cleared indications for use and does not alter the fundamental scientific technology of the device. The primary predicate is therefore the previous clearance of CADstream 5 in K081556. Table 1 includes several additional predicate devices cleared with substantially equivalent ADC features to those being implemented for CADstream 5.

Table 1: Predicate Devices

Manufacturer	Product	Cleared 510(k)	Product Code	Classification
Merge CAD Inc	CADstream 5	K081556	LLZ	2
Cedara	I-Response	K053301	LLZ	2
Medtronic	StealthViz	K081512	LLZ	2

11. Device Description

CADstream is an image processing system designed to assist in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream also is intended to provide workflow efficiency and interventional planning tools.

CADstream receives DICOM magnetic resonance images from a PACS or directly from the MRI scanner. As they are received, CADstream processes and displays the results on the CADstream server or a client personal computer.

Available features support:

- Visualization (standard image viewing tools, MIPs, and reformats)
- Analysis (registration, subtractions, coil inhomogeneity correction, kinetic curves, parametric image maps, apparent diffusion coefficient maps, automatic and manual segmentation and 3D volume rendering)
- Reporting of user-selected findings and assessment
- Interventional planning
- Workflow efficiency
- Communication and storage (DICOM import/export, query/retrieve, and study storage)

The CADstream system consists of proprietary software developed by Merge Healthcare installed on an off-the-shelf computer.

12. Indications for Use

CADstream is intended to be used in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream supports evaluation of dynamic MR data acquired during contrast administration. CADstream performs other user selected processing functions (such as image registration, subtractions, measurements, 3D renderings, and reformats).

CADstream also includes user-configurable features for reporting on findings in breast or general MRI studies. Additionally, CADstream assists users in planning MRI guided interventional procedures.

When interpreted by a skilled physician, this device provides information that may be used for screening, diagnosis, and interventional planning. Patient management decisions should not be made based solely on the results of CADstream.

CADstream may also be used as an image viewer of multi-modality, digital images, including ultrasound and mammography. CADstream is not intended for primary interpretation of digital mammography images.

13. Performance Testing

The subject device modification has undergone risk analysis to assess the impact of the modification on the device. Based on the risk analysis, verification testing was completed and results demonstrate that the predetermined acceptance criteria were met.

14. Conclusion

CADstream Version 5 provides features to integrate radiology department workflow by facilitating the visualization, analysis, and reporting of MR images. The potential hazards of adding the ADC map functionality have been studied and controlled as part of the product development process, including risk analysis and design considerations. The successful completion of verification testing has demonstrated conformance to design controls, user needs, and intended use, and that the device is safe and effective.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Brent Lewis
Director, Regulatory Affairs and Quality Assurance
Merge CAD, Inc. (formerly Confirma, Inc.)
11040 Main Street, Suite 100
BELLEVUE WA 98004

NOV - 6 2009

Re: K092954
Trade/Device Name: CADstream® Version 5
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 20, 2009
Received: October 29, 2009

Dear Mr. Lewis:

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indication(s) for Use Statement

510(k) Number: ~~TBD~~ K092954

Device Name: CADstream® Version 5

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092954