AUG - 6 2003

# 1 Summary of Safety and Effectiveness


**Submitter:** **Confirma, Inc.**
821 Kirkland Avenue
Kirkland, WA 98033-6318
Phone: (425) 576-1226
FAX: (425) 576-9295
www.confirma.com


**Date Prepared:** **July 11, 2003**


**Contact Person:** **Patricia A. Milbank**
Regulatory Consultant
Phone: (425) 497-1700 x116
pmilbank@spirationinc.com


**Device Trade Name: CADstream Version 2.0**

**Device Common Name: MRI Image Processing Software**

**Classification Name: 90 LLZ**

**Substantially Equivalent To:**

Vitrea 2: **K002519**
Vital Images
3300 Fernbrook Lane North
Suite 200
Plymouth, MN 55447-5341

AccuImage Image Display Software: **K961023**
AccuImage, Inc.
16303 Panormaic Way
San Leandro, CA 94578-1116

Siemens BOLD MRI: **K984221**
Siemens Corp
186 Wood Avenue, South
Iselin, NJ 08830

Voxar Plug n' View 3D: **K992654**
Voxar Limited
Bonnington Bond, 2
Anderson Place
Edinburgh, UK EH6 5 NP

Fusion 7D: **K020546**
Mirada Solutions Ltd
Mill Street
Oxford, UK OX2 OJX

K031779

**Intended Use Statement:**
CADstream is a Computer Aided Detection (CAD) system intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections).

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. CADstream can also be used to provide accurate and reproducible measurements of the longest diameters and volume of segmented tissues. Patient management decisions should not be made based solely on the results of CADstream analysis.

**Device Description**
The CADstream device relies on the assumption that pixels having similar MR signal intensities represent similar tissues. The CADstream software simultaneously analyzes the pixel signal intensities from multiple MR sequences and applies multivariate pattern recognition methods to perform tissue segmentation and classification.

The CADstream system consists of proprietary software developed by Confirma installed on an off-the-shelf personal computer and a monitor configured as an CADstream display station.

**Software Development**
The CADstream device has been designed, developed, tested and validated according to written procedures. These procedures identify functions within the organization responsible for developing and approving product specifications, coding and testing, verification and validation testing, and technical support.

**Performance**
The product has successfully completed the required integration and verification testing. Assessment of the product has been performed throughout the design development process in accordance with internal procedures and IEC 601-1-4.

**Clinical Evaluation**
Performance testing of the features described in the user manual has been successfully completed utilizing clinical datasets. Software beta testing also has been completed, validating that the requirements for these features have been met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Ms. Patricia A. Milbank
Regulatory Consultant
Confirma, Inc.
821 Kirkland Avenue, Suite 100
KIRKLAND WA 98033

Re: K031779
Trade/Device Name: CADstream™ Version 2.0
MRI Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 11 2003
Received: July 15, 2003

Dear Ms. Milbank:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

# FDA Indication for Use Form

**Applicant:** Confirma, Inc.

**510(k) Number (if known):** K031779

**Device Name: CADstream™ Version 2.0**

**Indication for Use:**

CADstream is a Computer Aided Detection (CAD) system intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections).

When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. CADstream can also be used to provide accurate and reproducible measurements of the longest diameters and volume of segmented tissues. Patient management decisions should not be made based solely on the results of CADstream analysis.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) _____
(Optional Format 1-2-96)

Prescription Use ✓

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031779