K04 1020

JUL - 7 2004

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. Identification of Submitter:

Name:	Patricia A. Milbank
Title:	Regulatory Consultant
Address:	Confirma 821 Kirkland Avenue Kirkland, WA 98033
Phone:	425-894-9733
Fax:	425-576-9295
Date Prepared:	April 15, 2004

2. Identification of Product:

Device name	CADstream™ Version 3.1
Classification:	21 CFR Section 892.1000
Manufacturer	Confirma, Inc.
Distributor	821 Kirkland Avenue Kirkland, WA 98033

3. Marketed Devices

The Confirma product is substantially equivalent to the devices listed below:

Model:	CADstream™ Version 2.0
Manufacturer:	Confirma, Inc.
510 (k) Number:	K031779
Model:	MICS Intervention Aid and MICS Intervention Aid PC-software package used to support stereotactic localization device
Manufacturer:	Machnet BV
510 (k) Number:	K020289
Model:	Software to support Stereotactic Localization Device (SLD) included in Phillips GYROSCAN NT system
Manufacturer:	Phillips Medical Systems
510 (k) Number:	K000832
Model:	Software to support MR Breast Biopsy Device included in Siemens MAGNETOM system
Manufacturer:	Siemens Medical Systems
510 (k) Number:	K010773

4. 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. CADstream is designed to analyze dynamic breast MRI studies.

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

The CADstream System consists of the following key components:

- A PC Server: a desk-side or rack mount PC capable of running the Server software, Client User Interface software, and Study Viewer software
- Server software: performs CADstream analysis and processing
- Client User Interface software: an administrative web page hosted on the Server
- Study Viewer software (CADalyst): an optional Image Viewer component, optimized for viewing breast MR studies processed by CADstream
- Archive System: a PC with CD burner and printer

In all cases, images are acquired and pushed to the CADstream system from the MR scanner. CADstream is configured to automatically process the images and create additional series. In this configuration, CADstream forwards the processed and original images to the existing softcopy reading station.

5. Indications 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 (in 2D or 3D) to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps, referred to as angiogenesis maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections).

CADstream also can be used to provide accurate and reproducible measurements of the longest diameters and volume of segmented tissues, including automated determination of volumes of interest (VOI), calculation of the longest diameter in X, Y and Z dimensions, the areas of VOI, the volume measurements of VOI (reported in cc), and 3D renderings of VOI.

The system includes an optional remote image viewer (CADalyst™), optimized for viewing breast MR studies processed by CADstream.

CADstream™ includes software to support the use of breast interventional coils and MR stereotactic localization devices to perform breast interventional procedures (SureLoc™). Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.

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

6. Comparison with Predicate Devices

CADstream Version 3.1 is substantially equivalent to the following software devices approved for use to support the use of breast biopsy coils and stereotactic localization devices by providing an automatic calculation of the location and depth of regions of interest, such as lesions or suspected lesions:

Model:	CADstream™ Version 2.0
Manufacturer:	Confirma, Inc.
510 (k) Number:	K031779
Model:	MICS Intervention Aid and MICS Intervention Aid PC-software package used to support stereotactic localization device
Manufacturer:	Machnet BV
510 (k) Number:	K020289
Model:	Software to support Stereotactic Localization Device (SLD) included in Phillips GYROSCAN NT system
Manufacturer:	Phillips Medical Systems
510 (k) Number:	K000832
Model:	Software to support MR Breast Biopsy Device included in Siemens MAGNETOM system
Manufacturer:	Siemens Medical Systems
510 (k) Number:	K010773

7. 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.

8. 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.

9. Clinical Evaluation

Performance testing of the features described in the user manual has been successfully completed utilizing clinical datasets. Software testing has been completed, through verification and validating testing, and the requirements for these features have been met. The potential hazards have been studied and controlled as part of the product development process, risk management activities, test and design considerations, and planned verification and validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

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

Re: K041020
Trade/Device Name: CADstream™ Version 3.1
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: April 19, 2004
Received: April 20, 2004

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 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 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

5 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA K041020

Device Name: CADstream™ Version 3.1

Indications for Use:

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

Prescription Use _√_ (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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041020