K013574

JAN 15 2002

Administrative Information

a. Summary of Safety and Effectiveness

1. Company Identification

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

2. Official Correspondent

Cheryl L. Shea
VP – RA/QA/CA
Phone: (425) 576-3247
cshea@confirma.com

3. Date of Submission: October 26, 2001

4. Device Trade Name: ACCENT™

5. Device Description

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

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

6. Intended Use

ACCENT™ is a computerized tissue segmentation device intended for use in conjunction with magnetic resonance (MRI) imaging data to identify similar tissue types. When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. ***ACCENT*** can also be used to provide accurate and reproducible measurements of the longest diameter and volume of identified tissue. Patient management decisions should not be made based solely on the results of ***ACCENT*** analysis.

7. Software

The *ACCENT* device developed and manufactured by Confirma, Inc. 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. Hazard Analysis

Hazard analysis on this product has been performed throughout the design development process in accordance with internal procedures and IEC 601-1-4. This process emphasizes:

- Identification of potential hazards, their causes, and their effects;
- Development of methodologies to control the occurrence of hazards and to mitigate their effects; and,
- Determination of any effect on patient safety and system effectiveness.

It is our conclusion that there is no hardware or software component integral to this device, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or serious injury to a patient. The "Level of Concern" is categorized as "Minor."

9. Substantial Equivalence

The intended use, design, function and performance characteristics for *ACCENT* are substantially equivalent to the following predicate devices:

- Vital Images Vitrea
- AccuImage Image Display Software
- Siemens BOLD MRI
- Voxar Plug n' View 3D

It is the opinion of Confirma, Inc. that ACCENT raises no new issues of safety and effectiveness as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2002

Ms. Cheryl Shea
Vice President, RA/QA/CA
Confirma
821 Kirkland Avenue
KIRKLAND WA 98033

Re: K013574
Trade/Device Name: Accent
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: October 26, 2001
Received: October 29, 2001

Dear Ms. Shea:

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

b. Indication for Use Form

510(k) Number (if known): K013574

Device Name: ***ACCENT™***

Indication for Use:

ACCENT™ is a computerized tissue segmentation device intended for use in conjunction with magnetic resonance (MRI) imaging data to identify similar tissue types. When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. ***ACCENT*** can also be used to provide accurate and reproducible measurements of the longest diameter and volume of identified tissue. Patient management decisions should not be made based solely on the results of ***ACCENT*** analysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013574