MAY 26 2005

K050846

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter:	The Medipattern Corporation
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Summary Date:	March 31, 2005

2. Identification of Product:

Device Name:	B-CAD System, Version 1.0
Device Common Name:	Picture and archive communications system
Device Classification:	21 CFR 892.2050, Class II, LLZ (90)
Manufacturer	The Medipattern Corporation

3. Marketed Devices

The B-CAD System provides viewing and post-acquisition image analysis of user-selected regions of interest on breast ultrasound images and automatically generates reports from user inputs annotated during the image analysis process. This software medical device is substantially equivalent to the devices listed below:

Model:	CADstream
Manufacturer:	Confirma, Inc.
510(k) Number:	K043216
Model:	QLAB Software
Manufacturer:	Phillips Ultrasound
510(k) Numbers:	K021966, K023877 and K040227

4. Device Description:

B-CAD is a computer-aided detection (CAD) software application, designed to assist radiologists to analyze breast ultrasound images. B-CAD automatically segments and classifies shape and orientation characteristics of user-selected regions of interest (ROI). The device uses multivariate pattern recognition methods to perform tissue segmentation and classification of images.

For breast ultrasound, these pattern recognition methods are used by a radiologist to analyze such features as shape and orientation [refer to American College of Radiology's (ACR) Breast Imaging Reporting and Data System (BI-RADS®) Breast Imaging Atlas and ACR-BI-RADS® Ultrasound lexicon].

The software application consists of proprietary software developed by The Medipattern Corporation. The software is a Windows 2000/XP, DICOM-compatible platform that may be installed on a standalone PC, PACS, or embedded in software applications cleared for use in medical imaging. The B-CAD user interface is designed to follow typical clinical workflow patterns to process, review, and analyze digital images.

The Medipattern software is designed to be compatible with any of the DICOM-compliant medical devices distributed by various OEM vendors.

To initiate B-CAD analysis and processing, images are acquired and pushed to the software application from an ultrasound imager for review and further analysis on a monitor. The user selects a ROI by clicking on a seed point and dragging the cursor to the selected boundary of the ROI. A circle appears, defining the region of interest. Once the ROI is selected, the B-CAD software initially displays a gallery of up to six segmented views on the monitor. The user may select any view for further analysis of anatomy and pathology. The software allows the user to annotate, tag, measure, and automatically record selected views. Results of the analysis are displayed on the monitor and may be selected by the user for automated reporting.

The software application automatically generates reports from user inputs annotated during the image analysis process. The user may select inputs for the report from various pull-down menus and toggle buttons and the user may direct the B-CAD software to prepopulate various fields contained in the report. All fields may be modified by the user at any time during the analysis and prior to archiving.

B-CAD includes the option to add annotations based on the ACR-BI-RADS® Breast Imaging Atlas. In addition, the report form has been designed to support compliance with the ACR-BI-RADS® Ultrasound Lexicon Classification Form.

An output may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or other DICOM device. The software may retrieve archived reports from a web server or other DICOM device.

5. Indications for Use

B-CAD is a computer-aided detection (CAD) software application designed to assist radiologists to analyze breast ultrasound images. B-CAD automatically segments and classifies shape and orientation characteristics of user-selected regions of interest (ROI).

The software allows the user to annotate, tag, measure, and automatically record selected views. The software automatically generates reports from user inputs annotated during the image analysis process. An output may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or other DICOM device. The software may retrieve archived reports from a web server or other DICOM device.

B-CAD includes the option to add annotations based on the ACR-BI-RADS® Breast Imaging Atlas. In addition, the report form has been designed to support compliance with the ACR-BI-RADS® Ultrasound Lexicon Classification Form.

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 solely on the results of B-CAD analysis. The ultrasound images displayed on B-CAD must not be used for primary diagnostic interpretation.

6. Comparison with Predicate Devices

The B-CAD System is substantially equivalent to software devices that provide display and post-acquisition image analysis of breast ultrasound images.

The image viewing capabilities of the B-CAD System are substantially equivalent to other commercially available image display products that have been cleared for use with ultrasound image files, specifically the CADstream, Version 4.0, software device manufactured by Confirma, and the QLAB software device manufactured by Phillips Ultrasound.

The Region of Interest quantification capabilities of the B-CAD software are substantially equivalent to other commercially available products that have been cleared for use with breast imaging studies, specifically the CADstream, Version 4.0, software device manufactured by Confirma, and the QLAB software device manufactured by Phillips Ultrasound.

The automated reporting features are substantially equivalent to other commercially available multi-modality products used for post-processing analysis, including CADstream, Version 4.0, manufactured by Confirma.

7. Performance Standards

No performance standards for PACS systems or components have been issued under the authority of Section 514.

8. General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the B-CAD software.

9. Software

Software development for the B-CAD System follows documented processes for software design, verification and validation testing. A risks assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product.

10. Conclusions

The B-CAD software is designed and manufactured to meet United States and international standards for the display and quantification of images acquired on ultrasound devices. The system is designed to incorporate components common to all image viewing systems including display, post-processing analysis, archiving, and retrieval capabilities within a clinical setting.

The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The System has been shown to be substantially equivalent to the predicate devices, and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Ms. Patricia A. Milbank
Regulatory Consultant
The Medipattern Corporation
2300 Sheppard Ave W Suite 204
Toronto, ON, M9M 3A4
CANADA

Re: K050846
Trade/Device Name: B-CAD System, Version 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 31, 2005
Received: April 6, 2005

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indication(s) for Use Statement

510(k) Number: K050846

Device Name: B-CAD System, Version 1.0

Indications for Use:

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

David A. Legorreta

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050846