SECTION 2: 510(K) SUMMARY AS REQUIRED BY CFR 807.92(c)

COMPANY NAME/ADDRESS/PHONE/FAX:

iCAD Inc.
98 Spit Brook Road, Suite 100
Nashua, NH 03062
T: 937-431-7945
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NAME OF CONTACT:

John A. DeLucia
VP, Regulatory Affairs and Quality Assurance

DATE:

January 29th, 2009

DEVICE NAME:

Breast Interventional Planning Software

TRADE NAME:

iCAD Breast Interventional Planning Software

COMMON NAME:

Software for Breast Interventional Planning

CLASSIFICATION NAME:

Picture archiving and communications system (21 CFR 892.2050, 90 LLZ)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQIVALENCE IS MADE

The iCAD Breast Interventional Planning Software (BIPS) is substantially equivalent to the following legally marketed predicate devices that analyze and display data for the purpose of planning interventional procedures based on MRI information.

510(k) Reference No.	Device Name	Software Module Used For Interventional Planning	Manufacturer
K043216	CADstream™ Version 4.0	SureLOC ™	Confirma, Inc.
K041286	DynaCAD™ V1.0	DynaLOC™	MRI Devices Corporation
K020289	MICS Intervention Aid	MICS-MIAS	Machnet BV

DEVICE DESCRIPTION

The iCAD Breast Interventional Planning Software (BIPS) is intended to extract certain image information and display them to a user. The software allows the user to select a target lesion in the breast as well as fiducial markers, and get accurate information about the optimal positioning of the biopsy needle or other interventional device, including visualization of the appropriate position, distances and other applicable settings. iCAD's BIPS is a software tool, which can assist the radiologist in planning and performing MRI guidance of percutaneous breast biopsies and other interventional procedures. When interpreted by a skilled physician, this device provides information that may be useful in interventional planning and monitoring.

The BIPS is a DICOM 3.0 compliant post-processing software package for viewing magnetic resonance imaging (MRI) data sets and supporting interventional breast coils and MR stereotactic localization devices when performing MRI-guided breast interventional procedures.

INDICATION FOR USE

The iCAD Breast Interventional Planning Software supports the use of interventional breast coils and MR stereotactic localization devices to perform magnetic resonance (MR) guided breast interventional procedures. 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 relative to the interventional device.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

The iCAD Breast Interventional Planning Software (BIPS) has the same intended use, principles of operation, and characteristics as the previously cleared predicate devices. iCAD's BIPS and each of the predicate devices named above are used to process and display, in a variety of formats, the information contained in MR datasets, calculate image coordinates for a user-defined region and fiducial markers, and display information that will assist the user in the performance of MR-guided interventional procedures. Although there are differences in the details of the visual interface of the iCAD BIPS and its predicate devices, those differences generally relate to the specific design outlay of each software package. The analysis performed and the information displayed by iCAD's BIPS does not raise new questions of safety or efficacy relative to the predicate devices.

GENERAL SAFETY AND EFFECTIVENESS CONCERNS:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA

Test data was supplied that met the requirements of the Software Test Plan and Software Unit Test Plan.

CONCLUSION:

This 510(k) Pre-Market Notification for the iCAD Breast Interventional Planning Software contains adequate information and data to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2009

Mr. John A. DeLucia
VP, RA/QA
iCad, Inc.
98 Spit Brook Road, Suite 100
NASHUA NH 03062

Re: K090223
Trade/Device Name: iCAD Breast Interventional Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 29, 2009
Received: February 3, 2009

Dear Mr. DeLucia:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

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

Indications for Use

510(k) Number (if known): K090223

Device Name: iCAD Breast Interventional Planning Software

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090223

(Posted November 13, 2003)