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

K091529

COMPANY NAME/ADDRESS/PHONE/FAX:

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AUG 0 4 2010

NAME OF CONTACT:

John A. DeLucia
VP, Regulatory Affairs and Quality Assurance

DATE:

May 21, 2009

DEVICE NAME:

Computed Tomographic Colonography Computer-Aided Detection Software

TRADE NAME:

iCAD VeraLook™ CTC CAD Software

COMMON NAME:

Software for Computed Tomographic Colonography Computer-Aided Detection

CLASSIFICATION NAME:

21 CFR 892.1750 Class II System, x-ray, tomography, computed JAK

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

iCAD's VeraLook™ CTC CAD Software is substantially equivalent to the following legally marketed predicate devices that display and visualize 2D and 3D medical image data of the colon derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of polyps.

510(k) Reference No.	Device Name	Manufacturer
K042674	Colon CAR 1.2	Medicsight
K042605	Syngo Colonography Software Package With Extended Functionality	Siemens Ag, Medical Solutions

DEVICE DESCRIPTION

The VeraLook is a software-based CAD system for detecting the location and extent of polyps in CTC exams. The product is intended to receive CTC images in standard DICOM format from any 3D workstation manufacturer, perform automated analysis on the images to identify polyps, and then produce information about the identified regions that can be received and displayed by CTC review workstations to help radiologists in the detection of polyps.

INDICATION FOR USE

VeraLook CTC CAD Software is intended to automatically detect potential polyps in CT Colonography exams. The identified polyps can then be highlighted to the interpreting physician after initial review of the CTC exam with the intent of identifying additional potential polyps that may not have been identified on initial review.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

VeraLook CTC CAD Software has similar intended use, principles of operation, features or and characteristics as the previously cleared predicate devices. VeraLook and each of the predicate devices are intended to detect, display, visualize, and measure colon lesions or polyps. VeraLook and the predicate devices all assist the radiologist in evaluating and confirming the presence or absence of colon lesions. VeraLook also shares common workflow features and characteristics as that of the predicate devices such as DICOM 3.0 Receiving, Polyp Size and Volume Measurement, and ability to generate reports.

VeraLook does differ from the predicates in that VeraLook expressly claims to identify "additional potential polyps that may not have been identified on initial review". This difference in intended use from the predicate devices could raise issues of safety and effectiveness. Recognizing this, iCAD has supplied clinical data in addition to bench testing and simulations to assess safety and effectiveness of this claim.

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 AND CLINICAL PERFORMANCE DATA

Non-clinical and clinical data was supplied to determine substantial equivalence to the predicate devices.

CONCLUSION:

This 510(k) Pre-Market Notification for iCAD's VeraLook CTC CAD Software contains adequate information and data to determine substantial equivalence to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. John A. DeLucia
Vice President Regulatory Affairs and Quality Assurance
iCAD, Inc.
98 Spitbrook Road, Suite 100
NASHUA NH 03062

AUG 04 2010

Re: K091529
Trade/Device Name: VeraLook™ CTC CAD
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 1, 2010
Received: February 2, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 1: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091529

Device Name: VeraLook™ CTC CAD

AUG 0 4 2010

Indications for Use:

iCAD's VeraLook™ CTC CAD is intended to automatically detect potential polyps in CT Colonography exams. The identified polyps can then be highlighted to the interpreting physician after initial review of the CTC exam with the intent of identifying additional potential polyps that may not have been identified on initial review.

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 (CDE)~~ OIVD

(Posted November 13, 2003)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K091529