SECTION 6: 510(K) Summary

510(k) OWNER and MANUFACTURER:

JUL 20 2012

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Registered Establishment Number: 1225671

NAME OF CONTACT:

Michael A. Patz
Senior Director, Clinical Affairs

DATE SUMMARY PREPARED:

May 21, 2012

TRADE NAME:

VersaVue Enterprise Suite

COMMON NAME:

MRI Analysis and Advanced Visualization Software

CLASSIFICATION:

CLASS II

CLASSIFICATION NAME:

Picture Archiving and Communications System

CRF CLASSIFICATION:

21 CFR 892.2050

PRODUCT CODE:

90 LLZ

SECTION 6: 510(K) Summary (con't)

6.1 Legally Marketed Devices to Which Substantial Equivalence is Claimed

iCAD's VersaVue Enterprise Suite consists of the MR Analysis Server Software and the VersaVue Enterprise Workstation Software, these two components are substantially equivalent to the following legally marketed predicate devices that post-process and display data based on magnetic resonance imaging (MRI) datasets.

Device Name	Software Purpose	Manufacturer	510(k) Reference #	Concurrence Date
3TP Software Option	MR image analysis	iCAD, Inc. (Formally CAD Sciences, Inc.	K031350	06/23/2003
3TP Workspace	MR image analysis	iCAD, Inc. (Formally CAD Sciences, Inc.	K050862	07/25/2005
Aegis	Auto contrast arrival	Sentinelle/ Hologic, Inc.	K070244	02/09/2007
Segasist P-AC 1.0	Segmentation assistant for prostate-auto-contouring	Segasist Technologies	K111311	10/17/11

TABLE 1: Legally Marketed Predicate Devices

6.2 Device Description

The VersaVue Enterprise Suite is intended for post-processing of MR datasets to provide a reliable means for visualizing MR datasets and supports the evaluation of dynamic and non-dynamic MRI datasets. It is also designed to provide study review and mathematical and/or statistical analysis. The VersaVue Enterprise Suite serves as a workflow roadmap tool that organizes and guides the radiologist through the series of sequential tasks that must be performed in order to arrive at a diagnosis.

This is the **same intended use** for the previously cleared 3TP predicate devices.

The VersaVue Enterprise Suite consists of the following two products; each product in turn incorporates individual modules:

1. MR Analysis Server Software consists of:
    - SpectraLook, for Breast MR analysis

- VividLook, for Prostate MR analysis
- OmniLook, for analysis of other MR datasets

2. VersaVue Enterprise Workstation Software
   - PrecisionPoint, for MR Breast Interventional Planning (K090223)

The MR Analysis Server Software is intended to be used as a post-processing software package designed to provide a reliable means for visualizing MR data. The data analysis supports the evaluation of dynamic and non-dynamic MR datasets. The MR Analysis Server software also analyzes contrast enhanced magnetic resonance imaging (DCE-MRI) studies. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto source MR images. In the hands of a trained physician the information provided by the software yields information that may assist in the interpretation of dynamic contrast enhanced studies.

The VersaVue Enterprise Workstation Software is intended for use in conjunction with SpectraLook, VividLook and OmniLook MR post-processing analysis software to provide study review and additional mathematical and/or statistical analysis. The Workstation software does not change the SpectraLook, VividLook or OmniLook software algorithm or the image series produced by the algorithm. It supports the analysis and presentation of the original MR datasets and the results generated by the software algorithm and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.

The Workstation software also works with iCAD's PrecisionPoint Breast Interventional biopsy software. The Breast Interventional Planning Software cleared under K090223 integrates intervention planning ability into the existing iCAD viewing workstation, allowing physicians to read images followed by subsequent planning of MRI-guided percutaneous breast biopsies and other interventional procedures. Biopsy planning, guidance and all necessary documentation are generated through the same Workstation interface.

6.3 "Indications for Use"

Indications for Use:

The VersaVue™ Enterprise Suite consists of the MR Analysis Server software and the VersaVue Enterprise Workstation software.

The MR Analysis Server software, which includes the SpectraLook®, VividLook® and OmniLook® modules is intended to be used as a post-processing software package designed to provide a reliable means for analyzing MR datasets. The software facilitates the analysis of

dynamic and non-dynamic MR datasets to provide study review and additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including parametric images overlaid onto source MRI images.

The VersaVue Enterprise Workstation software is intended for use in conjunction with the MR Analysis Server software and facilitates the analysis and presentation of datasets generated by the MR Analysis Server software and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.

The VersaVue Enterprise Suite serves as a workflow roadmap tool that organizes and guides the radiologist through the series of sequential tasks that must be performed in order to arrive at a diagnosis. The specific configuration of product features drives the Suite's underlying workflow solution for lesion characterization and reporting. This inherent workflow regimen integrates easily into the radiologist's existing departmental workflow and can be adapted to fit the needs of each user, thereby streamlining diagnosis. In the hands of a trained physician the information provided by the data analysis could yield information that may assist in the interpretation of dynamic and non-dynamic MR studies.

6.4 Summary of Changes

The iCAD VersaVue Enterprise Suite has the **same intended use**, **fundamental scientific technology**, and **characteristics** as the previously cleared predicate devices. However, the following features have been added as outlined below:

Feature	Predicate Devices			Change to Intended Use	Change to Fundamental Scientific Technology
	3TP Software Option and Workspace	Aegis	Segasist P-AC 1.0		
1. Graphical User Interface	X			No	No
2. Motion Correction	X			No	No
3. Tofts PK Model	X			No	No
4. Arterial Input Function	X			No	No
5. System Architecture	X			No	No
6. Apparent Diffusion Coefficient (ADC) Colorized Overlay	X			No	No
7. Contrast Arrival Detection		X		No	No
8. Prostate Segmentation (Semi-auto Contouring)			X	No	No

All of the added features are substantially equivalent to those in the predicate devices.

6.5 Summary of Technological Characteristics

The iCAD VersaVue Enterprise Suite has the **same intended use**, **fundamental scientific technology**, and characteristics as the previously cleared predicate devices. iCAD's VersaVue Enterprise Suite and each of the predicate devices named above in **Table 1** are used to process and display, in a variety of formats, the information contained in MR datasets, and provides a reliable means of visualizing MR data. DCE, other MR images and analysis results can be displayed in a variety of formats, including parametric images overlaid onto source MR images. The software also supports the analysis and presentation of data generated by the software algorithm and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.

6.6 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. Any potential hazards are controlled via software development, verification and validation testing.

6.7 Assessment of Non-Clinical Performance Data

Validation testing was performed according to a Software System Test Plan. All performance, functional and system requirement were met. Test data was used that met the requirements to validate system performance.

6.8 Conclusion

This Special 510(k) Device Modification for the VersaVue Enterprise Suite 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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iCAD, Inc.
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JUL 20 2012

Re: K121517
Trade/Device Name: VersaVue™ Enterprise Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 11, 2012
Received: July 13, 2012

Dear Mr. Patz:

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121517

Indications for Use

510(k) Number (if known): _____

Device Name: VersaVue™ Enterprise Suite

Indications for Use:

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The MR Analysis Server software, which includes the SpectraLook®, VividLook® and OmniLook® modules is intended to be used as a post-processing software package designed to provide a reliable means for analyzing MR datasets. The software facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review and additional mathematical and/or statistical analysis. The resulting analysis can be displayed in a variety of formats, including parametric images overlaid onto source MRI images.

The VersaVue Enterprise Workstation software is intended for use in conjunction with the MR Analysis Server software and facilitates the analysis and presentation of datasets generated by the MR Analysis Server software and incorporates the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.

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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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121517