iCAD, Inc
% Mr. John DeLucia
VP, Regulatory Affairs, Clinical Affairs and Quality Assurance
98 Spitbrook Road, Suite 100
NASHUA NH 03062

April 5, 2018

Re: K180125
Trade/Device Name: PowerLook Density Assessment Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 12, 2018
Received: January 16, 2018

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180125

Device Name
PowerLook Density Assessment Software

Indications for Use *(Describe)*
PowerLook Density Assessment is a software application intended for use with digital breast tomosynthesis synthesized 2D images from tomosynthesis exams. PowerLook Density Assessment provides an ACR BI-RADS Atlas 5th Edition breast density category to aid health care professionals in the assessment of breast tissue composition. PowerLook Density Assessment produces adjunctive information. It is not a diagnostic aid.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 1: 510k Summary

Prepared:

April 2, 2018

Submitter:

iCAD, Inc.
98 Spit Brook Road
Suite 100
Nashua, NH 03062

Contact Person:

John DeLucia
VP, Regulatory Affairs, Clinical Affairs and Quality Assurance
Email: jdelucia@icadmed.com
Phone: (603) 309-1945
Fax: (603) 880-3043

Submission Date:

January 12, 2018

Trade Name:

PowerLook Density Assessment Software

Common Name:

Medical Imaging Software

Classification Name

System, Image Processing, Radiological;
21 CFR 892.2050

Product Code

LLZ

Device Classification

Class II

SECTION 5: 510(K) Summary (con't)

Legally Marketed Devices to Which Substantial Equivalence is Claimed

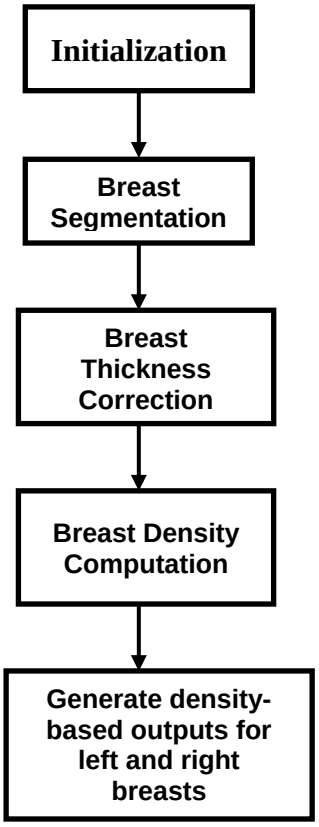
PowerLook Density Assessment Software is substantially equivalent to the following legally marketed predicate devices.

Device Name	Manufacturer	510(k) Reference #	Concurrence Date
iReveal V1.0*****	iCAD Inc.	K132742	December 3, 2013
Volpara Imaging Software	Matakina Technology	K152028	October 26, 2015

***** Cleared under the M-Vu Brand Name (VuCOMP Inc.) iCAD Acquired VuCOMP.

Device Description

The PowerLook Density Assessment Software analyzes digital breast tomosynthesis 2D synthetic images to calculate the dense tissue area of each breast. The measured dense tissue area is then used to provide a Category of 1-4 consistent with ACR BI-RADS 5th edition a-d. The top-level design sub-systems are as follows:



The assessment results in a final density map and, in conjunction with its pixel size (in square cm), is used to compute the area of the dense tissue (square cm). The area of the breast (square cm) is computed by counting the total number of pixels in the valid regions of the breast (using the breast segmentation mask). The ratio of the dense area to the total breast area gives the percent breast density (PBD) for the given view.

The dense areas, breast areas, percent breast densities, and dispersion for the CC and MLO views are averaged in order to report measurements for each breast. The average PBD and the average dispersion are then taken, and mapped to a density category from 1 through 4 consistent with ACR BI-RADS 5th edition a-d for each breast, using a set of calibrated boundaries. The higher category of the two breasts is reported as the overall case score.

The PowerLook Density Assessment is designed as a stand-alone executable operating within the larger software framework provided by PowerLook AMP[1]. As such, the PowerLook Density Assessment software is purely focused on processing tomosynthesis 2D synthetic images and is

[1] iCAD PowerLook AMP is a Class I medical device exempt per 21 CFR § 892.2010 (Medical image storage device) and 21 CFR § 892.2020 (Medical image communications device). The PowerLook AMP is a device that provides electronic storage functions for medical images and also provides electronic transfer of medical image data between medical devices.

not concerned with system issues such as managing DICOM image inputs or managing system outputs to a printer, PACS or Mammography Workstation. The PowerLook Density Assessment software is automatically invoked by PowerLook AMP.

The results of PowerLook Density Assessment are designed to display on a mammography workstation, high resolution monitor, or in a printed case report. PowerLook Density Assessment is designed to process approximately 60-120 cases per hour.

Intended Use / "Indications for Use"

PowerLook Density Assessment is a software application intended for use with digital breast tomosynthesis synthesized 2D images from tomosynthesis exams. PowerLook Density Assessment provides an ACR BI-RADS Atlas 5th Edition breast density category to aid health care professionals in the assessment of breast tissue composition. PowerLook Density Assessment produces adjunctive information. It is not a diagnostic aid.

Summary of Technological Characteristics

The technological characteristics of PowerLook Density Assessment Software are the same as the secondary predicate iReveal V1.0 cleared under K132742. Their major subsystems are the same except that:

1. For PowerLook Density Assessment intensity information is used to make the threshold adjustable and the intensity threshold process in iReveal V1.0 is not used.
2. The breast assessment method differs as well. iReveal V1.0 utilizes percentage of tissue that appears to be dense and PowerLook Density Assessment Software utilizes percentage and dispersion of tissue that appears to be dense.

The indications for use are similar to the primary predicate Volpara Imaging Software cleared under K152028.

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.

Assessment of Non-Clinical Performance Data

PowerLook Density Assessment Software has been verified and validated according to iCAD's design control processes. All supporting documentation has been included in this 510(k) Premarket Notification. Verification activity included unit, integration, and system level testing. Validation included the following:

PowerLook Density Assessment Software was run over a set of digital breast tomosynthesis synthesized 2D images from for which BI-RADS scores were obtained from radiologists followed by a comparison of the results between the predicate results, desired results, and observed performance for various parameters including kappa score, percent correct in each BI-RADS category, and combined A/B and C/D BI-RADS categories. PowerLook Density Assessment performed substantially equivalent to the predicate device.

- PowerLook Density Assessment Software is deployed on a DICOM platform that has been successfully tested for clinical network integration.

Comparison with Predicate Devices

The Summary of Substantial Equivalence Table below details the similarities and differences between PowerLook Density Assessment and the predicates. PowerLook Density Assessment has a similar indication as the primary predicate Volpara Imaging Software (K152028). They both calculate a density map to determine breast density from tomosynthesis exams. Volpara calculates a density map from tomosynthesis projection data and PowerLook Density Assessment calculates density map from tomosynthesis synthesized 2D images. From a technology standpoint, PowerLook Density Assessment is similar to iReveal V1.0 (K132742). Their major subsystems are the same except that for tomosynthesis synthetic 2D images (PowerLook Density Assessment), intensity information is used to make the threshold adjustable and the intensity threshold process is not used.

Conclusion:

Based upon the information presented in this submission, it is concluded that PowerLook Density Assessment Software is substantially equivalent to the named predicate devices.