iCAD, Inc.
% Ms. Heather Reed
Vice President, Quality Assurance and Regulatory Affairs
98 Spit Brook Rd. Suite 100
NASHUA NH 03062

July 12, 2021

Re: K211506
Trade/Device Name: PowerLook Density Assessment V4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: May 6, 2021
Received: May 14, 2021

Dear Ms. Reed:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K211506

Device Name
PowerLook Density Assessment V4.0

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."

510k Summary K211506

Date Prepared: May 7, 2021

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

Contact Person:
Heather Reed
Vice President, Quality Assurance and Regulatory Affairs
Email: hreed@icadmed.com
Phone: (603) 309-1945
Fax: (603) 880-3043

Device Name:

Trade Name:	PowerLook Density Assessment V4.0
Common Name:	Medical Imaging Software
Classification:	Medical Image Management and Processing System
Product Code:	QIH
Regulation Number:	21 CFR 892.2050
Review Panel:	Radiology

Predicate Device:

510k Number:	K180125
Manufacturer:	iCAD, Inc.
Device Name:	PowerLook Density Assessment, V3.4

Device Description

PowerLook Density Assessment 4.0 is a software application intended for use with mammography exams containing synthetic 2D images generated from Digital Breast Tomosynthesis (DBT) data. The PowerLook Density Assessment software assesses breast tissue composition and provides a breast density category aligned with BI-RADS® 5th Edition density lexicon. The PowerLook Density Assessment 4.0 algorithm is designed to be used with cases containing up to four synthetic 2D views. When exams contain only DBT and synthetic 2D images generated from DBT, the 4.0 algorithm is used. The PowerLook Density Assessment software is designed to work in conjunction with iCAD's PowerLook DICOM server platform, which is a Class I exempt medical device. The PowerLook Density Assessment 4.0 utilizes data management capabilities of PowerLook for controlling input to and output from the PowerLook Density Assessment algorithm. Results of the PowerLook Density Assessment

software application can be displayed on a mammography review workstation, mammography reporting application or radiology information system (RIS), or printed case report.

Technical Characteristics:
PowerLook Density Assessment V4.0 contains a new custom software application specifically designed to run on the PowerLook AMP, which is a Class I exempt medical device. The PowerLook Density Assessment utilizes data management capabilities of the PowerLook AMP for controlling input and output to the PowerLook Density Assessment. This functionality was validated to support the addition of GE V-Preview V4.1. This custom software application is new and independent from PowerLook Density Assessment V3.4 cleared in K180125.

Supported Digital Breast Tomosynthesis Systems

The following Digital Breast Tomosynthesis systems have been tested and are compatible with PowerLook Density Assessment V4.0 software:

- Hologic Selenia Dimensions/3Dimensions (C-View)
- GE Senographe Essential with SenoClaire (V-Preview)
- GE Senographe Pristina (V-Preview)

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.

Comparison with Predicate Device:

	***UNMODIFIED* Device** **PowerLook Density Assessment**	***MODIFIED* Device** **PowerLook Density Assessment V4.0**
Manufacturer	iCAD, Inc.	iCAD, Inc.
Classification Name	System, Image Processing, Radiological	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	QIH
510(k) #	K180125	Pending

	***UNMODIFIED* Device** **PowerLook Density Assessment**	***MODIFIED* Device** **PowerLook Density Assessment V4.0**
Intended Use / Indication 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.	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.
End User	Radiologists	Radiologists
Patient Population	Symptomatic and asymptomatic women undergoing mammography.	Symptomatic and asymptomatic women undergoing mammography.
Image Source Modalities	Synthetic views from tomosynthesis systems	Synthetic views from tomosynthesis systems
Input: Image Data Format	DICOM synthetic 2D images generated from breast tomosynthesis data	DICOM synthetic 2D images generated from breast tomosynthesis data
Output Format	DICOM structured report or DICOM secondary capture.	DICOM structured report or DICOM secondary capture.
Output Data	For each patient: • ACR BI-RADS® Atlas 5th Edition breast density category • Fractional indication of distance inside breast density category	For each patient: • ACR BI-RADS® Atlas 5th Edition breast density category • Fractional indication of distance inside breast density category
Deployment	Standalone computer	Standalone computer
Supported Digital Breast Tomosynthesis Systems	• Hologic Selenia Dimensions/3Dimensions (C-View) • GE Senographe Essential with SenoClaire (V-Preview) • GE Senographe Pristina (V-Preview)	• Hologic Selenia Dimensions/3Dimensions (C-View) • GE Senographe Essential with SenoClaire (V-Preview) • GE Senographe Pristina (V-Preview)

Summary of Indications for Use:
The "Indications for Use" remain unchanged from the Predicate *UNMODIFIED* Device PowerLook Density Assessment.

Summary of Technological Characteristic
Many technological characteristics of *Modified* PowerLook Density Assessment V4.0 remain unchanged from *Unmodified* Device PowerLook Density Assessment as the predicate. PowerLook Density Assessment V4.0 contains a new custom software application specifically designed to run on the PowerLook AMP, which is a Class I exempt medical device. PowerLook Density Assessment utilizes data management capabilities of the PowerLook AMP for controlling input and output to the PowerLook Density Assessment. This functionality was validated to support the addition of GE V-Preview V4.1. This custom software application is new and independent from PowerLook Density Assessment V3.4 cleared in K180125.

These changes do not raise different questions of safety and effectiveness.

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

Assessment of Non-Clinical Performance Data
PowerLook Density Assessment V4.0 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 regression testing was performed. Hologic C-View, GE V-Preview V3 and GE V-Preview V4.1 cases were run through Density Assessment 4.0, results were compiled into confusion matrices and then summarized. The performance of the system on all three datasets were above the desired performance, demonstrating that PowerLook Density Assessment 4.0 accurately calculates the BI-RADS breast density category for Hologic C-View and GE V-Preview data.

Conclusion:
Based upon the information presented in this submission, it is concluded that PowerLook Density Assessment V4.0 is substantially equivalent to the named predicate device.