



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

March 12, 2021

Re: K203822

Trade/Device Name: ProFound AI® Software V3.0
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological computer assisted detection and diagnosis software
Regulatory Class: Class II
Product Code: QDQ
Dated: February 16, 2021
Received: February 22, 2021

Dear Heather 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

Indications for Use

510(k) Number (if known)
K203822

Device Name
ProFound AI® Software V3.0

Indications for Use (Describe)

ProFound AI® V3.0 is a computer-assisted detection and diagnosis (CAD) software device intended to be used concurrently by interpreting physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and calcifications that may be confirmed or dismissed by the interpreting Physician

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.

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510k Summary K203822

Date Prepared: February 16, 2021

Submitter:

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

Contact Person:

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Vice President, Quality Assurance and Regulatory Affairs
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Device Name:

Trade Name: ProFound AI[®] Software V3.0
Common Name: Medical Imaging Software
Classification: Radiological Computer Assisted Detection and Diagnosis Software
Product Code: QDQ
Regulation Number: 21 CFR 892.2090
Review Panel: Radiology

Predicate Device:

510k Number: K191994
Manufacturer: iCAD, Inc.
Device Name: ProFound AI[®] V2.1

Device Description

The ProFound AI[®] V3.0 device detects malignant soft-tissue densities and calcifications in digital breast tomosynthesis (DBT) images. The ProFound AI V3.0 software allows an interpreting physician to quickly identify suspicious soft tissue densities and calcifications by marking the detected areas in the tomosynthesis images. When the ProFound AI V3.0 marks are displayed by a user, the marks will appear as overlays on the tomosynthesis images. Each detected finding will also be assigned a “score” that corresponds to the ProFound AI V3.0 algorithm’s confidence that the detected finding is a cancer (Certainty of Finding). Certainty of Finding scores are a percentage in range of 0% to 100% to indicate CAD’s confidence that the finding is malignant. ProFound AI V3.0 also assigns a score to each case (Case Score) as a percentage in range of 0% to 100% to indicate CAD’s confidence that the case has malignant findings. The higher the Certainty of Finding or Case Score, the higher the confidence that the detected finding is a cancer or that the case has malignant findings.

Technical Characteristics:

Lesion Detection

ProFound AI V3.0 software detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D digital breast tomosynthesis images. The ProFound AI algorithm uses deep learning technology to process feature computations and uses pattern recognition to identify suspicious breast lesions appearing as soft tissue densities or clusters of calcifications. Each detected region in the tomosynthesis data is identified or represented by marking the contour of the lesion in the tomosynthesis slice where it was detected.

Certainty of Finding Scores

Certainty of Finding scores are relative scores assigned to each detected region and a Case Score is assigned to each case regardless of the number of detected regions. Certainty of Finding and Case Scores are computed by the ProFound AI algorithm and represent the algorithm's confidence that a specific finding or case is malignant. The scores are represented on a 0% to 100% scale. Higher scores represent a higher algorithm confidence that a finding or case is malignant. Lower scores represent a lower algorithm confidence that a finding or case is malignant. The scores are based on a population with 50% prevalence of cancer and should be interpreted as the probability of the finding or case correctly being identified as malignant in a population of 50% cancers and 50% non-cancers. The scores serve as a guide to interpreting physicians to aid in determining if a suspicious finding or case needs further work-up. **These scores are not intended to be the clinically used "probability of malignancy"**. Certainty of Finding and Case Scores are not calibrated to the prevalence in the intended use population or to the prevalence in the pivotal reader study outlined in the Assessment of Non-Clinical Performance Data section, and consequently, the Certainty of Finding and Case Scores are in general higher than the actual probability of malignancy in an intended use population with less than 50% prevalence. These scores represent a relative level of concern or level of suspicion because they do not represent an absolute clinical probability of malignancy.

Case Score

Each tomosynthesis study is assigned a Case Score. Case Scores are the CAD algorithm's confidence that a study contains a malignant finding. Case Scores are represented on a 0%-100% scale. Higher Case Scores represent a higher confidence that the case contains a malignant finding. Lower Case Scores represent a lower confidence that the case contains a malignant finding.

Supported Digital Breast Tomosynthesis Systems

The following Digital Breast Tomosynthesis systems have been tested and are compatible with ProFound AI V3.0 software:

- Hologic Selenia Dimensions/ 3Dimensions (Standard Resolution)
- GE Senographe Essential with SenoClaire
- GE Senographe Pristina
- Siemens Inspiration both Standard and Empire Reconstruction

- Siemens Revelation both Standard and Empire Reconstruction

Intended Use / “Indications for Use”

ProFound AI® V3.0 is a computer-assisted detection and diagnosis (CAD) software device intended to be used concurrently by interpreting physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and calcifications that may be confirmed or dismissed by the interpreting Physician.

Comparison with Predicate Device:

	<i>UNMODIFIED</i> Device ProFound™ AI V2.1	<i>MODIFIED</i> Device ProFound™ AI V3.0
Manufacturer	iCAD, Inc.	iCAD, Inc.
Classification Name	Radiological Computer Assisted Detection and Diagnosis Software	Radiological Computer Assisted Detection and Diagnosis Software
Regulation Number	21 CFR 892.2090	21 CFR 892.2090
Product Code	QDQ	QDQ
510(k) #	K191994	Pending
Intended Use / Indication for Use	ProFound™ AI V2.1 is a computer-assisted detection and diagnosis (CAD) software device intended to be used concurrently by interpreting physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and calcifications that may be confirmed or dismissed by the interpreting Physician.	ProFound AI® V3.0 is a computer-assisted detection and diagnosis (CAD) software device intended to be used concurrently by interpreting physicians while reading digital breast tomosynthesis (DBT) exams from compatible DBT systems. The system detects soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices. The detections and Certainty of Finding and Case Scores assist interpreting physicians in identifying soft tissue densities and calcifications that may be confirmed or dismissed by the interpreting Physician.
End User	Radiologists	Radiologists
Patient Population	Symptomatic and asymptomatic women undergoing mammography.	Symptomatic and asymptomatic women undergoing mammography.

	<i>UNMODIFIED</i> Device ProFound™ AI V2.1	<i>MODIFIED</i> Device ProFound™ AI V3.0
Mode of Action	Image processing device intended to aid in the detection, localization, and characterization of soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices.	Image processing device intended to aid in the detection, localization, and characterization of soft tissue densities (masses, architectural distortions and asymmetries) and calcifications in the 3D DBT slices.
Image Source Modalities	Digital breast tomosynthesis slices	Digital breast tomosynthesis slices
Output Device	Softcopy Workstation	Softcopy Workstation
Deployment	Standalone computer	Standalone computer
Supported Digital Breast Tomosynthesis Systems	<p><u>ProFound AI V2 Software:</u></p> <ul style="list-style-type: none"> • Hologic Selenia Dimensions/3Dimensions • GE Senographe Essential with SenoClaire • GE Senographe Pristina <p><u>ProFound AI V2.1 Software:</u></p> <ul style="list-style-type: none"> • Siemens Inspiration both Standard and Empire Reconstruction • Siemens Revelation both Standard and Empire Reconstruction 	<p><u>Profound AI V3.0 Software:</u></p> <ul style="list-style-type: none"> • Hologic Selenia Dimensions/3Dimensions • GE Senographe Essential with SenoClaire • GE Senographe Pristina <p><u>ProFound AI V2.1 Software:</u></p> <ul style="list-style-type: none"> • Siemens Inspiration both Standard and Empire Reconstruction • Siemens Revelation both Standard and Empire Reconstruction

Summary of Indications for Use:

The “Indications for Use” remain unchanged from the Predicate *UNMODIFIED* Device ProFound AI V2.1.

Summary of Technological Characteristic

The technological characteristics of *Modified* Device, ProFound AI V3.0 remain unchanged from *Unmodified* Device ProFound AI V2.1 as the predicate. Per 21 CFR 892.2090, both devices are radiological computer assisted detection and diagnostic software intended to aid in the detection, localization, and characterization of disease specific findings on acquired medical images. The outputs of both devices serve as a secondary or concurrent read and not a primary read. The output is used to inform the interpreting physician (who themselves make the primary diagnostic and patient management decisions) and will not replace the clinical expertise and judgment of the clinical user.

The difference in technological characteristics of ProFound AI V3.0 and the predicate device are software improvements leading to improved specificity for GE and Hologic modalities. 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. In addition, general controls of the FD&C Act, and special controls established for Radiological Computer Assisted Detection and Diagnosis Software are in place to further mitigate any safety and or effectiveness risks.

Assessment of Non-Clinical Performance Data

ProFound AI V3.0 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. Lastly, ProFound AI V3.0 is deployed on a DICOM platform that has been successfully tested for clinical network integration.

Hologic DBT Non-clinical Validation Testing:

ProFound AI V3.0 Hologic Supplemental Standalone Study compared performance of ProFound AI V3.0 with Hologic DBT images to the baseline performance of ProFound AI V2 with Hologic DBT images in terms of case sensitivity, FP rate per 3D volume and Area Under the localized Receiver Operating Characteristic (ROC) Curve (AUC).

The conclusion of non-inferiority of the standalone performance of ProFound AI V3.0 with a Hologic DBT screening population compared to the baseline performance of ProFound AI V2 with a Hologic DBT screening population is that the claims established in the original Pivotal Reader Study described in 0074-6003, PowerLook® Tomo Detection V2 Pivotal Reader Study Clinical Study Report (CSR) (K182373) also apply to ProFound AI V3.0 with Hologic DBT.

A paired comparison assessed the performance of ProFound AI V3.0 on Hologic DBT images to the performance of ProFound AI V2.0 on the same set of Hologic DBT images and demonstrated a significant increase in specificity from V2.0 to V3.0.

GE DBT Non-clinical Validation Testing:

ProFound AI V3.0 GE Supplemental Standalone Study compared performance of ProFound AI V3.0 with GE DBT images to the baseline performance of ProFound AI V2 with Hologic DBT images in terms of case sensitivity, FP rate per 3D volume and AUC.

The conclusion of non-inferiority of the standalone performance of ProFound AI V3.0 with a GE DBT screening population compared to the baseline performance of ProFound AI V2 with a Hologic DBT screening population is that the claims established in the original Pivotal Reader Study described in 0074-6003, PowerLook® Tomo Detection V2 Pivotal Reader Study Clinical Study Report (CSR) (K182373) also apply to ProFound AI V3.0 with GE DBT.

A paired comparison assessed the performance of ProFound AI V3.0 on GE DBT images to the performance of ProFound AI V2.0 on the same set of GE DBT images and demonstrated a significant increase in specificity from V2.0 to V3.0.

Conclusion:

Based upon the information presented in this submission, it is concluded that ProFound AI V3.0 is substantially equivalent to the named predicate device.