February 23, 2018

Densitas, Inc.
% Mr. Ken Pilgrim
Director - RA & QA
Emergo Group, Inc.
2500 Bee Cave Road, Building 1, Suite 300
AUSTIN TX 78746

Re: K170540
Trade/Device Name: DM-Density
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 9, 2018
Received: February 13, 2018

Dear Mr. Pilgrim:

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,

Michael D. O'Hara 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)*
K170540

Device Name
DM-Density

Indications for Use *(Describe)*
DM-Density is a software application intended for use with compatible full field digital mammography systems. DM-Density calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. DM-Density provides these numerical values for each breast as well as a density category to aid interpreting physicians in the assessment of breast tissue composition. DM-Density 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.

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Section 5 – 510(k) Summary

K170540

Submitter: Densitas, Inc.
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Date Prepared: 12 Feb 2018

Contact Person: Emergo Global Consulting, LLC
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Contact: Ken Pilgrim, Sr. RA / QA Consultant
Email: project.management@emergogroup.com

Submission Date: January 16, 2017

Trade Name: DM-Density

Common Name: Medical Imaging Software

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050
LLZ

Device Classification: Class II

Predicate Device(s): iReveal® by iCAD, Inc. (formerly M-Vu® by VuCOMP, Inc.)
K132742

Description of Device:

DM-Density is a standalone software application that automatically analyzes "for presentation" full field digital mammograms to calculate breast tissue composition.

The software processes full field digital mammograms according to proprietary algorithms and generates a Breast Density Grade in accordance with the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) density classification scales.

DM-Density has been validated on Hologic's Selenia Dimensions and Lorad Selenia systems.

DM-Density data output is packaged for viewing on a mammography workstation or PACS as a DICOM mammography Structured Report or Secondary Capture. Output may also be transmitted to a RIS. DM-Density reports are configured to provide the following data based on the two available breast density classification grades:

<u>BI-RADS 4th Edition</u>

For each breast:

- Area of fibroglandular tissue (cm^2)
- Area of breast (cm^2)
- Area-based breast density (%)

For each patient: DM-Density breast density grade and percent breast density

<u>BI-RADS 5th Edition</u>

For each patient: DM-Density breast density grade

Alternative configuration options are available to match user preferences.

DM-Density can process approximately 600 cases per hour.

Indications for Use Statement:

DM-Density is a software application intended for use with compatible full field digital mammography systems. DM-Density calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. DM-Density provides these numerical values for each breast as well as a density category to aid interpreting physicians in the assessment of breast tissue composition. DM-Density produces adjunctive information. It is not a diagnostic aid.

Substantial Equivalence Discussion:

DM-Density and iReveal (formerly M-Vu Breast Density) calculate breast density as a ratio of fibroglandular tissue and total breast area estimates. Both devices are not to be used as diagnostic aids, but to provide adjunctive information only. Users in both cases must be qualified medical practitioners and exercise their professional judgment when formulating diagnostic decisions and selecting appropriate treatment paths that are supported by breast density data. Both devices are DICOM-compliant and rely on DICOM imaging data from digital mammography systems (data input).

Table 5A – Comparison of Characteristics

Manufacturer	**510(K) Submitter**	**Predicate**	**Significant Differences**
	Densitas, Inc.	**iCAD, Inc. (formerly VuCOMP, Inc.)**	
Trade Name	**DM-Density**	**iReveal (formerly M-Vu Breast Density)**	
510(k) Number	N/A	K132742	N/A
Product Code	LLZ	LLZ	N/A
Regulation Number	21 CFR Part 892.2050	21 CFR Part 892.2050	N/A
Regulation Name	System, Image Processing, Radiological	System, Image Processing, Radiological	N/A
Intended Use / Indications for Use	DM-Density is a software application intended for use with compatible full field digital mammography systems. DM-Density calculates percent breast density defined as the ratio of fibroglandular tissue to total breast area estimates. DM-Density provides these numerical	M-Vu Breast Density is a software application intended for use with digital mammography systems. M-Vu Breast Density calculates breast density as a ratio of fibroglandular tissue and total breast area estimates. M-Vu Breast Density provides these numerical values for each	N/A

	values for each breast as well as a density category to aid interpreting physicians in the assessment of breast tissue composition. DM-Density produces adjunctive information. It is not a diagnostic aid.	breast as well as a density category to aid radiologists in the assessment of breast tissue composition. M-Vu Breast Density produces adjunctive information. It is not an interpretive or diagnostic aid.	
Patient Population	Symptomatic and asymptomatic women undergoing mammography	Same	N/A
End Users	Interpreting Physicians	Same	N/A
Image Source Modalities	Hologic Selenia Dimensions	All digital radiography (DR) systems and computed radiography (CR) systems	N/A – Suite of image source modalities that are compatible with iReveal include the source modalities compatible with DM-Density.
	Hologic Lorad Selenia		
Input: Image Data Format	DICOM full field digital mammography imager – For Presentation; RCC, LCC, RMLO, LMLO	DICOM digital mammography imager – For Processing; RCC, LCC, RMLO, LMLO	DM-Density = For Presentation; iReveal = For Processing
Output Data	**BI-RADS 4th Ed.** For each breast: ● Area of fibroglandular tissue (cm^2) ● Area of breast (cm^2) ● Area-based breast density (%) For each patient: DM-Density breast density grade and percent breast density **BI-RADS 5th Ed.** For each patient: DM-Density breast density grade	For each breast: ● Area of fibroglandular tissue (cm^2) ● Area of breast (cm^2) ● Area-based breast density (%) For each patient: VuCOMP density grade/BIRADS breast density	Subject device provides breast density grade consistent with BI-RADS 5th Ed.; Predicate device does not conform to the 5th Ed. scale.

Measurement Scales	4-category breast density scale from 4th Ed. ACR BI-RADS Atlas 2003	4-category breast density scale from 4th Ed. ACR BI-RADS Atlas 2003	Subject device provides users with the option of utilizing either the 4th or 5th edition scales; Predicate Device utilizes 4th edition scale only
	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013		
Output Device	Mammography Workstation, PACS, and RIS	Same	N/A
Output Format	DICOM Structured Report and Secondary Capture	Same	N/A
Deployment	Standalone computer	Same	N/A
Data Throughput	600 cases per hour	60 – 120 cases per hour	N/A
Assessment scope	Results per image	Same	N/A
Assessment type	Area-based	Same	N/A
Anatomical Location	Breast	Same	N/A

Clinical Performance Data:

There was no human clinical testing required to support the medical device.

Non-Clinical Performance Data:

Results from internal verification and validation testing performed in accordance with Densitas' design control processes confirm that DM-Density product specifications have been met. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device.

Verification testing consisted of unit and integrated system level testing. A risk analysis in accordance with ISO 14971 was completed as part of the software design and development effort. Validation testing relied on expert radiologist visual assessments of mammography density, and is summarized as follows:

- Reliability was assessed using the Pearson's Correlation Coefficient by comparing the DM-Density percent density, dense breast area and total area measurements for Left and Right breasts as well as for CC and MLO views.
- Accuracy was assessed by validating DM-Density percent density and total area measurements. The accuracy of DM-Density dense breast area measurements follows by implication.
- Accuracy was further assessed by validating the Breast Density Grade assessments to known Breast Density Grade assessments using the Kappa statistic.
- Reproducibility was assessed with the Pearson Correlation Coefficient using a dataset from subjects who had two mammograms acquired on compatible mammography acquisition systems within a two year time period.
- The inverse relationship between breast density and age was assessed by calculating the Pearson's Correlation Coefficient between DM-Density percent density measures and age at time of screening.

Statement of Substantial Equivalence:

DM-Density, as designed and developed by Densitas Inc., is determined to be substantially equivalent to the predicate device. Differences between the two devices do not raise new questions about the safety and effectiveness of DM-Density.