Densitas, Inc.
℅ Alex Morris
Director, Programs & Regulatory Affairs
#66, 1344 Summer Street
Halifax, NS B3H 0A8
CANADA

February 19, 2020

Re: K192973
Trade/Device Name: densitas densityai™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 13, 2020
Received: February 18, 2020

Dear Alex Morris:

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 and Part 809); 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)*
K192973

Device Name
densitas densityai™

Indications for Use *(Describe)*
Densitas densityai™ is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Densitas densityai™ provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Densitas densityai™ 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 - Special 510(k) Summary

K192973

Submitter: Densitas, Inc.
#66, 1344 Summer Street
Halifax, NS, B3H 0A8 Canada

Date Prepared: 06-Feb-2020

Contact Person: Contact: Alex Morris, Dir., Programs and Regulatory Affairs
Direct: 647-470-4363
Office: 902-405-4610
Email: alex@densitas.health

Submission Date: 21-Oct-2019

Trade Name: densitas density**ai**™ (formerly DM-Density™) 2.5.0

Common Name: Medical Imaging Software

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

Device Classification: Class II

Predicate Device(s): DM-Density™ 2.1.0b K170540

No reference devices were used in this submission

Description of Device:

Densitas density**ai**™ is a standalone software application that automatically analyzes "for presentation" data from digital breast x-ray systems, including digital breast tomosynthesis exams, to assess breast tissue composition.

The software processes the data 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) 5th edition density classification scale.

Densitas density**ai**™ 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. Densitas density**ai**™ reports are configured to provide the following data based on the BI-RADS 5th edition breast density classification grade:

BI-RADS 5th Edition
For each patient: DENSITAS breast density grade (BDG)

Alternative configuration options are available to match user preferences.
Densitas density**ai**™ can process approximately 600 cases per hour.

Indications for Use Statement:

Densitas density**ai**™ is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Densitas density**ai**™ provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Densitas density**ai**™ produces adjunctive information. It is not a diagnostic aid.

Comparison with Predicate device:

The focus of this submission is to introduce compatibility with new digital breast x-ray systems, including digital breast tomosynthesis.

Table 1 – Comparison of Characteristics

Manufacturer	**510(K) Submitter**	**Predicate**	**Significant Differences**
	Densitas, Inc.	**Densitas, Inc.**	
Trade Name	densitas density**ai**™ (formerly DM-Density™)	DM-Density™	
510(k) Number	K192973	K170540	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	Densitas density**ai**™ is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Densitas density**ai**™ provides an ACR BI-RADS Atlas 5th Edition breast density category to aid interpreting physicians in the assessment of breast tissue composition. Densitas density**ai**™ produces adjunctive information. It is not a diagnostic aid.	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.	Addition of breast tomosynthesis systems
Patient Population	Symptomatic and asymptomatic women undergoing mammography	Symptomatic and asymptomatic women undergoing mammography	N/A
End Users	Interpreting Physicians	Interpreting Physicians	N/A
Image Source Modalities	**FFDM** Hologic Selenia Dimensions Hologic Lorad Selenia GE Senographe Essential GE Senographe Pristina Siemens MAMMOMAT Inspiration Siemens MAMMOMAT Novation DR Siemens MAMMOMAT Fusion Siemens MAMMOMAT Inspiration Prime Siemens MAMMOMAT Revelation **Synthetic 2D** Hologic C-View	Hologic Selenia Dimensions Hologic Lorad Selenia	Addition of new FFDM scan types and synthetic 2d compatibility
Input: Image Data Format	DICOM digital mammography imager – For Presentation; RCC, LCC, RMLO, LMLO	DICOM full field digital mammography imager – For Presentation; RCC, LCC, RMLO, LMLO	similar
Output Data	**BI-RADS 5th Ed.**	**BI-RADS 4th Ed.** For each breast: ● Area of fibroglandular tissue (cm^2)	Removed BI-RADS 4th edition compatibility

	For each patient: densitas density**ai**™ breast density grade	• Area of breast (cm²) • 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	
Measurement Scales	4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013	4-category breast density scale from 4th Ed. ACR BI-RADS Atlas 2003 4-category breast density scale from 5th Ed. ACR BI-RADS Atlas 2013	Removed BI-RADS 4th edition compatibility
Output Device	Mammography Workstation, PACS, and RIS	Mammography Workstation, PACS, and RIS	N/A
Output Format	DICOM Structured Report and Secondary Capture	DICOM Structured Report and Secondary Capture	N/A
Deployment	Standalone computer	Standalone computer	N/A
Data Throughput	600 cases per hour	600 cases per hour	N/A
Assessment scope	Results per image	Results per image	N/A
Assessment type	Image feature-based	Area-based	Adjusted to reflect shift to image feature-based assessment type
Anatomical Location	Breast	Breast	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 densitas density**ai**™ product specifications have been met. Supporting documentation is included in this Special 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 densitas densityai™ percent density, dense breast area and total area measurements for Left and Right breasts.
- Accuracy was assessed by validating densitas densityai™ percent density and total area measurements. The accuracy of densitas densityai™ 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 by running the algorithm twice over the same set of images.
- The inverse relationship between breast density and age was assessed by calculating the Pearson's Correlation Coefficient between densitas densityai™ percent density measures and age at time of screening for data sets where age was known.

Densitas results were compared to a consensus assessment of four expert radiologists' independent readings of overall breast composition on a large dataset that spanned all compatible scanner types. Results for individual (Table 2) and grouped categories (Table 3) are summarized below.

Table 2 - 4 X 4 confusion matrix for the density software and the reference standard using the BI-RADS 5th edition breast density scale (A,B,C,D) (all scan types)

n=796; Kappa 0.87 (0.87, 0.87)						
		the density software				
		A	**B**	**C**	**D**	Accuracy
Radiologist Consensus	**A**	72	20	0	0	78%
	B	23	225	47	0	76%
	C	0	16	262	37	83%
	D	0	0	10	84	89%
	Total	95	261	319	121	

Table 3 - Confusion matrix for the density software and the reference standard using the BI-RADS 5th edition breast density scale grouped into Fatty (A,B) and Dense (C,D) density categories (all scan types)

n=796; Kappa 0.84 (0.8, 0.88)				
		the density software		Accuracy
		Fatty (A,B)	**Dense (C,D)**	
Consensus Radiologist	**Fatty (A,B)**	340	47	88%
	Dense (C,D)	16	393	96%
	Total	356	440	

Statement of Substantial Equivalence:

Densitas density**ai**™(formerly DM-Density) 2.5.0, is determined to be substantially equivalent to the predicate device, DM-Density 2.1.0b. Differences between the two devices do not raise new questions about the safety or effectiveness of the software.