VMI Tecnologias LTDA
% Daniel Kamm
Principal Engineer
Kamm and Associates
8870 Ravello Ct
NAPLES FL 34114

March 1, 2022

Re: K210151
Trade/Device Name: Digimamo D
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: January 26, 2022
Received: January 28, 2022

Dear Daniel Kamm:

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,

Jessica Lamb, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210151

Device Name
DIGIMAMO D

Indications for Use *(Describe)*
The Digimamo D ® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The Digimamo D is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Digimamo D is intended to be used in the same clinical applications as traditional film/screen systems.

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.

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510(k) Summary: 510(k) Number K210151

VMI Tecnologias LTDA
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Dist. Ind. Genesco Aparecido De Oliveira,
Lagoa Santa, Minas Gerais, Brazil
Date Prepared: February 24, 2022
Contact: Siele Santos
Tel: Tel: +55 (31) 3681-6388

1. **Identification** of the Device:
   Trade/Device Name: Digimamo D
   Regulation Number: 892.1715
   Regulation Name: Full Field Digital, System, X-Ray, Mammographic
   Regulatory Class: II
   Product Code: MUE
   Common/Usual Name: Digital Mammography System

2. Equivalent legally marketed device: K172027, Adani
   Trade/Device Name: MammoScan
   Regulation Number: 892.1715
   Regulation Name: Full Field Digital, System, X-Ray, Mammographic
   Regulatory Class: II
   Product Code: MUE
   Common/Usual Name: Digital Mammography System

3. **Reference Devices:** We employ the imaging panel/software cleared by DRTECH in RSM2430C (K170930). We meet the hardware and software requirements expressed in that submission.
   Regulation Number: 21 CFR 892.1715
   Regulation Name: Full-field digital mammography system and
   Picture archiving and communications system
   Regulatory Class: II
   Product Code: MUE

4. **Indications for Use:** The Digimamo D ® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The Digimamo D is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Digimamo D is intended to be used in the same clinical applications as traditional film/screen systems. .

5. **Description of the Device**: This is a mammography system available in only a digital version. The main characteristics are:
   Operation Panel/Console:
   Natively, the Digimamo D Generator operation panel is integrated into the imaging system so that all indications and technical selections for radiographic exposure will be shown on the monitor, in conjunction with the image acquired.

X-ray tube information:
The X Radiation Emitters (Target) are available in Tungsten.

Filter Selection:

- Tungsten Target: For radiation beam filter selection, there is a choice of Silver (50µm) or rhodium (50µm) filters, use the key to select the desired filter.

- Molybdenum Target: For radiation beam filter selection, there is a choice of Molybdenum (30µm) or rhodium (25µm) filters, use the key to select the desired filter.

The type in use is indicated on the operation panel, and there is the option of automatic selection based on kV.

Window Material and thickness: 0.5mm Be

Focal Spot Sizes: Small focus: 0,1mm, Large Focus: 0,3mm

Operating principle:
The general sequence of events in the patient examination procedure and the flow of image data from detector to the final image: (This operating principle is identical to the predicate)
1. User turns on the power.
2. User turns on the collimation light.
3. Patient is positioned.
4. Breast compression is done.
5. Operator initiates the exposure.
6. Initiation of the exposure turns on the x-ray source and the digital image panel acquires the x-ray and breast is decompressed.
7. Image is converted by the panel to digital image format, which in turn is transferred to the internal processor for storage and subsequent display.

Radiological Characteristics:
Power: 5 kW kV's range: 20 to 40, with increments in AEC mode of 0.1 kV and digital mode of 1 kV.
mA Ranges (25, 32, 80, 125, 140) with automatic selection depending on focus and selected kV and exposure mode.
Selection of automatically defined times according to the selected Mas and mA. Synchronized system between the emitter and the X-ray receiver. mAs ranges (0.25 to 630) and (5 to 400) in Manual and AEC modes respectively.
Automatic exposure Control (AEC) provides: Auto mode: The system automatically calculates the kV and mAs Semi-Automatic mode: The system automatically calculates the mAs. The kV is selected by the operator.
Manual mode: The kV and the mAs are selected by the operator. The density selection: Adjustable in 11 levels (from-5 to + 5) being the default density (0). Adjustments are made directly to the Control Panel.

All control is accomplished through a CPU (workstation) integral part of Digimamo D.

Column and Gantry

The column and arm tube Assembly of Digimamo D, was designed to offer all the comfort and safety in performing mammography exams. Smooth movements with fast and accurate acceleration and deceleration ramps.

The control panels located on the right and left sides enable: Position the arm automatically at 45 degrees clockwise and counterclockwise.

Rotate the arm left and right (-180 º, 0 º, + 180 º).

Move the arm vertically.

Select the positioning of the AEC (automatic exposure control).

Light the collimator lamp.

Select to more or less breast compression stop point.

Removable face protector.

Informative display.

Compression fine adjustment knobs (both sides).

Handles for hands (both sides).

Emergency button (both sides).

Support attachment points for magnification factors of 1.5 and 1.8 times.

Bucky/Digital Panel 24x30 cm, equipped with 335 l/pol. anti-diffuser grids and 5:1 ratio in carbon fiber.

Flat Panel Detector

CsI Scintillator

Active area of 291.8 x 233.5 mm

Resolution of 3,840(W) x 3,072(L) pixels

Pixel size: 76 µm.

Depth (A/D): 16 bits.

Carbon fiber cover.

Synchronized drive system with the X-ray emitter assembly.

Fully integrated image detection system (native) to the equipment platform and digital imaging acquisition and treatment software.

Workstation

Core i7 processor; 1 TB capacity hard drive; 8 GB RAM memory; Windows Professional operating system; . 23-inch, high-resolution, touchscreen LED Monitor; Reader unit and CD/DVD burner; Digital Image Acquisition Software.

6. Substantial Equivalence Chart: See next page

Characteristic	K172027, Adani MammoScan	Reference Device DRTECH in RSM2430C (K170930).	Digimamo D
Indications for Use:	The MammoScan® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The MammoScan is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoScan is intended to be used in the same clinical applications as traditional film/screen systems.	The RSM 2430C is a detector indicated for use in screening and diagnostic mammography.	The Digimamo D ® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The Digimamo D is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Digimamo D is intended to be used in the same clinical applications as traditional film/screen systems. (SAME)
Photo			
X-ray Generator	High Frequency 10 kW	Not included	High Frequency 5 kW.

Characteristic	K172027, Adani MammoScan	Reference Device DRTECH in RSM2430C (K170930).	Digimamo D
kV Range	20-50 kV with 0.1 kV step	kVp 20 to 35(Mo), 28 to 39(Rh)	kV's range: 20 to 40, with increments in AEC mode of 0.1 kV and digital mode of 1 kV
mA Range	5-250 mA, From 5 mA to 80 mA in 0.1 mA steps and from 80 mA to 250 mA in 1 mA steps	-	25, 32, 80, 125, 140 with automatic selection depending on focus and selected kV and exposure mode.
mAs Ranges	0.1 to 1200 mAs	3 to 500 mAs	0.25 to 630 and 5 to 400 in Manual and AEC modes respectively
Detector Information			
	Adani MammoScan (K172027)	DRTECH RSM2430C (K170930)	Digimamo D
Detector	Teledyne CCD LN-40-08K05-00-R	DRTECH RSM2430C (K170930)	DRTECH RSM2430TD (same detector as K170930 in a different enclosure)
Configuration	Scanning imaging principle, 2x2 binning	Rectangular Flat Panel	Rectangular Flat Panel
Pixel Size	54 µm in normal operation mode	76 µm	76 µm
Pixel Matrix	8192 (H) x 256 (V) (Scanning required)	3072 x 3,840 (Single exposure, no scanning required)	3072 x 3,840 (Single exposure, no scanning required)
Detector Size	221 mm long active area	240 x 300 mm, Greater active area	240 x 300 mm, Greater active area
Scintillator	CsI	CsI SAME	CsI SAME
A/D	16 Bits	16 Bits. SAME	16 Bits. SAME
Panel Interface	Ethernet	Ethernet SAME	Ethernet SAME
Meets US Performance Standard	YES	N/A	YES
Power Source	AC Line Only	SAME	SAME

7. **The technological characteristics**, including design, materials, composition, and energy source, are substantially the same, so there are no issues impacting safety and effectiveness.

8. **Safety and Effectiveness**, comparison to predicate device. The results of bench testing AND clinical testing indicate that the new devices are as safe and effective as the predicate device. Proper system operation is fully verified upon installation. We verified that this combination of components worked properly and produced diagnostic quality mammographic images. The key image acquisition component is the RSM2430TD digital x-ray receptor panel (K170930) manufactured by DRTECH. It is electronically identical to the RSM2430C panel cleared in K170930 (different enclosure) with the SAME PRODUCT CODE: MUE.

9. **Summary of non-clinical testing:** Systems were assembled and tested and found to be operating properly. Firmware was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* We also observed the requirements of this guidance document: *Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Full-Field Digital Mammography System Document issued on: November 5, 2010.*
Because the system uses Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.* In addition, we reviewed the FDA guidance *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff* and added a supplement to our user manual. The digital panel software employed was already reviewed by FDA in the reference submission list, above. Labeling is in accordance with the US Performance Standard.
This device complies with all applicable requirements of 21 CFR 1020.30, and 1020.31

   Digimamo D has been tested by 3rd party Nationally Recognized Testing Laboratories to be in compliance with the following International Standards:

   1. IEC 60601-1: 2010 + Aml:2016 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

   2. IEC 60601-1-2:2010 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests

   3. IEC 60601-1-3: 2011 + Aml:2016 Medical Electrical Equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment;

   4. IEC 60601-2-28:2012 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

   5. IEC 60601-2-45: 2013 + Aml:2017 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-Ray equipment and stereotactic mammographic devices.

10. **Summary of clinical testing**: Clinical testing was required to establish substantial equivalence because of the requirement in the FDA Guidance Document cited above. Sixty images were evaluated by three Board Certified US based radiologists. Images were taken during the standard screening procedure in Fundação Municipal de Saúde de Macaé, Rio de Janeiro, Brazil. Totally, there are 12 sets of images presented in this review. Images were selected in order to represent different categories in density and BIRADS categories. Each set consists of four standard views (right CC, right MLO, left CC, left MLO.) If requested by the radiologist, additional image with magnification was taken. Images were reviewed by US-based MQSA quaified radiologists. The results of clinical image evaluation determined that the clinical images reviewed by the expert radiologists were of sufficiently acceptable quality for mammographic usage.

11. **Conclusion:** After analyzing bench and clinical tests, it is the conclusion of VMI Tecnologias LTDA that the new Digimamo D System is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.