DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2016

STATLIFE
% Mrs. Robyn Bonnett
Authorized Correspondent
EPIDEMIO3D
50 Milk Street, 16th Floor
BOSTON MA 02109

Re: K152009
Trade/Device Name: DENSEEMAMMO v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 20, 2016
Received: October 24, 2016

Dear Mrs. Bonnett:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152009

Device Name
DENSEEMAMMO v1.0

Indications for Use *(Describe)*

DenSeeMammo is a software application intended for use with digital mammography systems. DenSeeMammo estimates BI-RADS breast density value by analyzing processed digital 2D mammograms using a fully automated comparison procedure.

DenSeeMammo provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density.

DenSeeMammo produces adjunctive information. It is not an interpretive or diagnostic aid when the final assessment of breast density category is made by an MQSA qualified interpreting physician. DenSeeMammo core software has been built and tested on OS X based computers.

DenSeeMammo graphical use interface software has been built and tested on Windows, OS X and Linux based computers.

DenSeeMammo is compatible for images obtained from GE Senographe Essentials 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

1 Submitter Information

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Phone	+33 682 437 010

2 Trade name and Common name

Trade Name:	DenSeeMammo
Software Version:	1.0
Common Name:	Imaging Software

3 Device Classification

Regulatory Class:	II
Classification Panel:	Radiology;
Product Code:	LLZ
Classification:	System, Image Processing, Radiological: 21 CFR § 892.2050

4 Identification of Predicate Device

The predicate device used for DenSeeMammo software is the following device:
K102556 (October 7, 2010) – VOLPARA Imaging Software (MATAKINA Technology Limited)

5 Device Description

DenSeeMammo analyzes processed digital 2D mammograms in a fully automated comparison procedure that produces a BI-RADS breast density value.
DenSeeMammo handles processed images extracted from DICOM files as input.
DenSeeMammo core software has been built and tested on OS X based computers.
DenSeeMammo graphical user interface software has been built and tested on Windows, OS X and Linux based computers.
DenSeeMammo software is a component which accepts digital mammography images as an input. The software processes and analyses the image according to proprietary algorithms which allow comparison to qualified databases containing images previously quoted by radiologists.

For each patient it provides measures of BI-RADS breast density category. DenSeeMammo provides results per patient based on the maximum density category of the two breasts.
The patient population is symptomatic and asymptomatic women undergoing mammography.
The software does perform illustrative image display but only for illustrative purposes and not for interpretation or diagnostic.

6 Indications for Use

DenSeeMammo is a software application intended for use with digital mammography systems.

DenSeeMammo estimates BI-RADS breast density value by analyzing processed digital 2D mammograms using a fully automated comparison procedure.

DenSeeMammo provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density.

DenSeeMammo produces adjunctive information. It is not an interpretive or diagnostic aid when the final assessment of breast density category is made by an MQSA qualified interpreting physician.

DenSeeMammo core software has been built and tested on OS X based computers.

DenSeeMammo graphical use interface software has been built and tested on Windows, OS X and Linux based computers.

DenSeeMammo is compatible for images obtained from GE Senographe Essentials systems.

7 Technological Characteristics

DenSeeMammo is a software that aims at assessing the breast density of a woman. The software use processed digital 2D mammograms in a fully automated comparison procedure that produces a BI-RADS breast density value. The software processes and analyses the image according to proprietary algorithms which allow comparison to qualified databases containing images previously quoted by radiologists. For each patient it provides measures of BI-RADS breast density category. DenSeeMammo provides results per patient based on the maximum density category of the two breasts.

The software works in a client-server mode and requires that the user computer is on the same local network as the server. Computations are made on the server part of the system that also provide the graphical user interface to display the results. A web browser is required to display the graphical user interface: to select the patients' images and to display the assessment of the breast density according to the BI-RADS standards and the similar images.

The software was developed using the Java-1.8 language as a 3-component web application (See 11.1 Components). The software was developed following an adapted version of the model – view – controller software architectural pattern.

The device does not contact the patient, nor does it control any life-sustaining devices.

8 Substantial Equivalence

The comparison of the proposed device with the predicate device warrants a determination of substantial equivalence when considered in combination with the test results and technical information provided in this 510(k) Premarket Notification. Both devices are labeled as providing adjunctive information which is not an interpretive or diagnostic aid.

Table 1 Substantial Equivalence comparison table

Characteristics	**DENSEEMAMMO v1**	**VOLPARA ™ Imaging Software K102556**
Classification	LLZ 892.2050	LLZ 892.2050
Software level of concern	Moderate	Moderate
Device type	Not an interpretive or diagnostic aid.	Not an interpretive or diagnostic aid.
Intended Use	DenSeeMammo is a software application intended for use with digital mammography systems. DenSeeMammo estimates BI-RADS breast density value by analyzing processed digital 2D mammograms using a fully automated comparison procedure. DenSeeMammo provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density. DenSeeMammo produces adjunctive information. It is not an interpretive or diagnostic aid when the final assessment of breast density category is made by an MQSA qualified interpreting physician. DenSeeMammo core software has been built and tested on OS X based computers. DenSeeMammo graphical use interface software has been built and tested on Windows, OS X and Linux based computers.	Volpara is a software application intended for use with digital mammography systems. Volpara calculates density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values for each image to aid radiologists in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid. Volpara is a software application which runs on Windows or Linux-based computers.
Intended users	Radiologists	Radiologists
Patient population	Symptomatic and asymptomatic women undergoing mammography	Symptomatic and asymptomatic women undergoing mammography
Image source	Digital mammography images	Digital mammography images
Compatibility	GE Digital Mammography systems	GE and Hologic Digital Mammography systems

Characteristics	DENSEEMAMMO v1	VOLPARA ™ Imaging Software K102556
Anatomical area	Breast	Breast
Assessment scope	Provides results per patient based on the maximum density category of the two breasts	Provides results per image (per each breast)
Assessment type	Comparison to qualified databases containing images previously quoted by MQSA radiologists using ACR BI-RADS V recommendations	Volumetric
Measures provided	For each breast: BI-RADS V breast density category For each patient: BI-RADS V breast density value	For each breast: → Volume of fibro glandular tissue → Volume of breast → Breast density For each patient: VOLPARA density grade/BIRADS breast density
Operating environment	Software core: OS X based computers Software graphical user interface: Windows, OS X or Linux based computers	Windows or Linux-based computers
Deployment	Stand-alone computer	Stand-alone computer

9 Performance Testing

The DenSeeMammo software has been verified and validated according to the company's design control process and particularly according the IEC 62304 standard. A risk analysis compliant with ISO 14971 has been provided. Software testing included both unit level and integrated system level testing.

Verification bench testing of DenSeeMammo breast density software included:

- DenSeeMammo was run over twice on a data sets of images to test reproducibility.

- DenSeeMammo was run over on a sample of exams and left and right breast densities were compared to test reproducibility.

- DenSeeMammo results were compared to visual assessment from MQSA radiologists.

- DenSeeMammo was run over substantial data sets of images, which had been previously visually assessed by MQSA radiologists.

Clinical validation testing of DenSeeMammo breast density software included:

Beta site testing to assess the ability of physicians to successfully integrate the software into their existing systems as well as assess usability for target users.

All verification and validation testing was successful in that established acceptance criteria was met for all of the tests conducted.

10 General Safety and Effectiveness Concerns

The device 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 potential hazards. These potential hazards are controlled via software development, verification and validation testing.

11 Conclusions Drawn from Studies

The results demonstrate that the DenSeeMammo device is substantially equivalent to the predicate device in function and indications for use.