



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

June 26th, 2018

Re: K173574

Trade/Device Name: DenSeeMammo
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 29, 2018
Received: May 31, 2018

Dear Mrs. Hélin:

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 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,



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

Indications for Use

510(k) Number
K173574

Device Name
DenSeeMammo

Indications for Use (Describe)

DenSeeMammo is a software application intended for use with Full Field Digital Mammography systems. DenSeeMammo estimates BI-RADS breast density category 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 a diagnostic aid since 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 and Hologic Selenia Dimension 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Prepared June 20, 2018

1 Submitter Information

Company Name: STATLIFE
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Authorized Correspondent Valérie Hélin, Director of medical and regulatory affairs
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2 Trade name and Common name

Trade Name: DenSeeMammo
Software Version: 1.2
Common Name: Imaging Software

3 Device Classification

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

4 Identification of Predicate Device

The modified software is substantially equivalent to DenSeeMammo Software version 1.0 cleared pursuant to K152009 cleared December 5th, 2017

5 Predicate Device Description

DenSeeMammo analyzes processed digital 2D mammograms in a fully automated comparison procedure that produces a BI-RADS breast density category.

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 visually assessed 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 Comparison with Predicate device

DenSeeMammo software version 1.2 works in the same way as DenSeeMammo software 1.0 but is updated to make it compatible with digital mammograms from Hologic mammography systems and can work with a pair of images composed of two views (craniocaudal (CC) and mediolateral oblique (MLO)) or with an image composed of one view (CC for GE images, and CC or MLO for Hologic images).

Table 1 Substantial Equivalence comparison table

Characteristics	Predicate Device DENSEMAMMO v1.0 (K152009)	Submission Device DENSEMAMMO v1.2
Classification	LLZ 892.2050	LLZ 892.2050
Software level of concern	Moderate	Moderate
Device type	Not an interpretive or diagnostic aid	Not a diagnostic aid
Intended Use	<p>DenSeeMammo is a software application intended for use with digital mammography systems.</p> <p>DenSeeMammo estimates BI-RADS breast density value by analyzing processed digital 2D mammograms using a fully automated comparison procedure.</p> <p>DenSeeMammo provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density.</p> <p>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.</p> <p>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.</p>	<p>DenSeeMammo is a software application intended for use with Full Field Digital Mammography systems.</p> <p>DenSeeMammo estimates BI-RADS breast density category by analyzing processed digital 2D mammograms using a fully automated comparison procedure.</p> <p>DenSeeMammo provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density.</p> <p>DenSeeMammo produces adjunctive information. It is not a diagnostic aid since the final assessment of breast density category is made by an MQSA qualified interpreting physician.</p> <p>DenSeeMammo core software has been built and tested on OS X based computers.</p> <p>DenSeeMammo graphical use interface software has been built and tested on Windows, OS X and Linux based computers.</p> <p>DenSeeMammo v1.2 is compatible for images obtained from GE Senographe Essentials and Hologic Selenia Dimension systems.</p>
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
Anatomical area	Breast	Breast
Assessment scope	Provides results per patient based on the maximum density category of the two breasts	Provides results per patient based on the maximum density category of the two breasts
Assessment type	Comparison to qualified databases containing images previously visually assessed by MQSA-qualified radiologists using ACR BI-RADS V recommendations	Comparison to qualified databases containing images previously visually assessed by MQSA-qualified radiologists using ACR BI-RADS V recommendations

Characteristics	Predicate Device DENSEEMAMMO v1.0 (K152009)	Submission Device DENSEEMAMMO v1.2
Measures provided	For each breast: BI-RADS V breast density category For each patient: BI-RADS V breast density category	For each breast: BI-RADS V breast density category For each patient: BI-RADS V breast density category
Operating environment	Software core: OS X based computers Software graphical user interface: Windows, OS X or Linux based computers	Software core: OS X based computers Software graphical user interface: Windows, OS X or Linux based computers
Deployment	Stand-alone computer	Stand-alone computer

7 Indications for Use

DenSeeMammo is a software application intended for use with Full Field Digital Mammography systems.

DenSeeMammo estimates BI-RADS breast density category 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 a diagnostic aid since 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 v1.2 is compatible for images obtained from GE Senographe Essentials and Hologic Selenia Dimension systems.

8 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 category. The software processes and analyses the image according to proprietary algorithms that allow comparison to qualified databases containing images previously visually assessed 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 be 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.

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.

In addition to the verification and validation testing conducted for the specific modification to the software detailed in this 510(k), complete verification and validation data testing conducted for the predicate was repeated in order to ensure integration and backwards compatibility.

Verification bench testing included:

- DenSeeMammo v1.2 software was run over twice on data sets of images to test reproducibility.
- DenSeeMammo v1.2 software was run over on a sample of exams and left and right breast densities were compared to test reproducibility.
- DenSeeMammo v1.2 software results were compared to visual assessment from MQSA-qualified radiologists.
- DenSeeMammo v1.2 software was run over substantial data sets of two views images (CC + MLO) from GE and Hologic systems, which had been previously visually assessed by MQSA-qualified radiologists.
- DenSeeMammo v1.2 software was run over substantial data sets of one view images from GE (CC) and Hologic (CC or MLO) systems, which had been previously visually assessed by MQSA-qualified radiologists. Visual assessments were performed from two views CC + MLO images.

Clinical validation testing 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 510(k) Premarket Notification for DenSeeMammo v1.2 contains adequate information and data to demonstrate substantial equivalence to the predicate device.