



Food and Drug Administration
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Matakina Technology Ltd.
% Ralph Highnam, Ph.D.
CEO
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NEW ZEALAND

January 7, 2016

Re: K153427
Trade/Device Name: Volpara Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 19, 2015
Received: November 25, 2015

Dear Dr. Highnam:

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

Indications for Use

510(k) Number (if known)

K153427

Device Name

Volpara Imaging Software

Indications for Use (Describe)

Volpara is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara calculates and quantifies a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category to aid health care professionals in the assessment of breast tissue composition. Volpara is not an interpretive or diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made by an MQSA qualified interpreting physician.

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 13th November 2015

Sponsor: Matakina Technology Limited

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Submission Date: 16th November 2015

Device Name: Volpara Imaging Software

Common Name: Imaging Software

Classification:

Regulatory Class: II

Review Category: Class II

Classification Panel: Radiology

System, Imaging Processing; 21 CFR 892.2050; LLZ

Legally Marketed Predicate Devices:

The modified software, Volpara Imaging Software (“Volpara”) 1.5.2 is substantially equivalent to the Volpara Imaging Software 1.5.1 cleared pursuant to K152028 (Matakina Technology Limited) on October 26th, 2015, which serves as the primary predicate, as well as K102556 cleared on 7th October, 2010.

Predicate Device Description:

Volpara Imaging Software 1.5.1 generated and validated density maps from digital x-ray images of the breast and from those density maps computed various quantitative density-map based statistics, for example, volume of fibroglandular tissue in cm³, volume of breast in cm³, and their ratio, the volumetric breast density, and then provided a mechanism to generate a Breast Imaging-Reporting and Data System (BI-RADS) breast density category from the volumetric breast density.



Volpara Imaging Software 1.5.1 operates on a Windows server that meets Volpara data input and output requirements and generally is located outside the patient environment.

Comparison with Predicate Device:

Volpara Imaging Software 1.5.2 works in the same way as Volpara Imaging Software 1.5.1 but also provides the density maps via user selectable viewing options along with additional quantitative statistics computed on the density map.

Substantial Equivalence Comparison Table

	Predicate Device Volpara, 1.5.1 (K152028)	Submission Device, Volpara 1.5.2
Intended Use (difference is underlined)	“Volpara is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara calculates a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values along with a BI-RADS breast density 4 th or 5 th Edition category to aid health care professionals in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid“	“Volpara is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara calculates and quantifies a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values along with a BI-RADS breast density 4 th or 5 th Edition category to aid health care professionals in the assessment of breast tissue composition. Volpara is not an interpretive or diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made by an MQSA-qualified interpreting physician.”
Intended Users	Health Care Professionals	Health Care Professionals
Image Source	Digital mammography images	Digital mammography images.
Image Sources	Digital mammograms from mammography or tomosynthesis systems.	Digital mammograms from mammography or tomosynthesis systems.
Anatomical Area	Breast	Breast
Assessment Scope	Volumetric	Volumetric
Operating Environment	Windows	Windows
Image Storage and Report Generation	Yes Output to the console	Yes Output to the console
Numeric Output	Volume of Fibroglandular tissue Volume of Breast	Volume of Fibroglandular tissue Volume of Breast



	Volumetric Breast Density BIRADS 4 th or 5 th Edition Breast Density Category	Volumetric Breast Density BIRADS 4 th or 5 th Edition Breast Density Category Average thickness of dense tissue Maximum thickness of dense tissue (and location). Maximum volume of dense tissue above any 1cm ² square region (and location).
Image Output	None	Density map in DICOM SCI format, for visualization as user requires.
Classification	21 CFR 892.2050; LLZ	21 CFR 892.2050; LLZ
Software Level of Concern	Moderate	Moderate

Intended Use:

Volpara is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara calculates and quantifies a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category to aid health care professionals in the assessment of breast tissue composition. Volpara is not an interpretive or diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made by an MQSA-qualified interpreting physician.

Device Description

The Volpara 1.5.2 software provides volumetric assessment of digital x-ray images of the breast, including in that definition both digital mammograms and raw tomosynthesis projections. The assessment takes the form of generating and validating density maps where the value at each pixel represents the thickness of fibroglandular tissue between that pixel and the x-ray source. From those density maps various quantitative density-map based statistics are computed, namely:

- volume of fibroglandular tissue in cm³,
- volume of breast in cm³
- the volumetric breast density in %,
- a BI-RADS 4th Edition or 5th Edition breast density category
- average thickness of dense tissue
- maximum thickness of dense tissue
- maximum volume of dense tissue above any 1cm² square region



The device outputs those numbers along with the density maps themselves marked with the location of the various maxima.

Volpara operates on a Windows server that meets Volpara data input and output requirements and generally is located outside the patient environment. The device does not contact the patient, nor does it control any life-sustaining devices.

Performance Data

The Volpara software has been verified and validated according to the company's design control process. All of the documents specified in FDA's various software guidance documents have been submitted in the Special 510(k) Notification. A risk analysis compliant with ISO 14971 has been provided and incorporated into the development effort. Software testing included both unit level and integrated system level testing. A report of outstanding anomalies was included in the software information.

The modified device was tested and determined to be compliant to the following standards: ISO 14971:2012 Medical devices – Application of risk management to medical devices; ISO 62304-2006 Software Life Cycle Processes, DICOM 2015.

In addition to the verification and validation testing conducted for the specific modification to the software detailed in this Special 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:

- Measurement accuracy was assessed by comparing Volpara estimates with known values from breast phantoms.
- Relationship to ground truth was assessed by running Volpara over x-ray images of breasts for which there was 3D breast MRI data available with a comparison of estimates of fibroglandular tissue.
- Reproducibility was assessed by running Volpara over substantial datasets where we have the women's age and results compared with the expected and known decrease in breast density with age.
- Reproducibility was assessed by running Volpara over substantial data sets and the results for left and right breasts and CC and MLO views were compared to confirm that the results were similar for each view and each breast.
- Reproducibility was assessed by running Volpara over substantial data sets where the same woman had been imaged on GE and Hologic systems one year apart and the results were compared to confirm they were similar.

- Reproducibility was assessed by running over substantial data sets where the same woman had been imaged on one of GE, Hologic and Siemens tomosynthesis-compatible units running in both tomosynthesis and mammography modes, and the results were compared to confirm they were similar.
- Relationship to visual assessment was assessed by running Volpara over x-ray images for which a BI-RADS 4th and 5th Edition density category was available from MQSA qualified radiologists followed by a comparison of the two sets of data.

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
- Beta site testing to collect minimum, average and maximum Volpara breast densities and compare these to other existing databases

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

General Safety and Effectiveness Concerns:

The device labeling 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.

Conclusion:

The 510(k) Premarket Notification for Volpara contains adequate information and data to demonstrate substantial equivalence to the predicate device.