



September 21, 2018

Volpara Health Technologies Limited
Ralph Highnam
CEO
Level 7, 44 Victoria Street, Wellington Central
WELLINGTON, 6011
NEW ZEALAND

Re: K182310

Trade/Device Name: Volpara Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 3, 2018
Received: August 24, 2018

Dear Ralph 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <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,

A handwritten signature in black ink, appearing to read "Rob A. Ochs", is written over a large, light blue, semi-transparent watermark of the letters "FDA".

for
Robert A. 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)
K182310

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.

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Special 510(k) Summary
Prepared 15th August 2018

Sponsor: Volpara Health Technologies

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Submission Date: 15th August 2018

510(k) submission number: K182310

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”) 1.5.6 is substantially equivalent to the original Volpara Imaging Software 1.5.2 cleared pursuant to K153427 (Volpara Health Technologies Limited), which serves as the primary predicate.

Predicate Device Description:

The Volpara Imaging Software (“Volpara”) 1.5.2 software provides volumetric assessment of digital x-ray images of the breast, including in that definition both raw digital

mammograms and raw tomosynthesis projections (the central projections of which are just raw digital mammograms).

The assessment takes the form of generating and validating density maps wherein the value at each pixel represents the thickness of fibroglandular tissue between that pixel and the x-ray source.

From the density maps various quantitative density-map based statistics are computed as follows:

- volume of fibroglandular tissue in cm³
- volume of breast in cm³,
- the volumetric breast density (the percentage of fibroglandular tissue in breast)
- average thickness of dense tissue in cm
- maximum thickness of dense tissue in cm
- maximum volume of dense tissue above any 1cm² square region (or “focal density”)

From the volumetric breast density, a BI-RADS 4th Edition and 5th Edition breast density category can be attained by applying thresholds set by the software.

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

Volpara Imaging Software 1.5.2 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.

Comparison with Predicate Device:

Volpara Imaging Software 1.5.6 is the same core software as the predicated device Volpara Imaging Software 1.5.2 with the addition of the following software and labeling enhancements.

- The modified software uses the focal density information when generating a BI-RADS breast density category.
 - The modified software supports data acquired using Hologic’s SmartCurve paddle.
 - The modified software provides output image quality metrics which were validated but not output by 1.5.2.
 - The User Manual has been expanded to cover the modifications described above, and with an updated bibliography.
 - The software provides an option to select highlighting of density scores at a specified threshold.
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Substantial Equivalence Comparison Table

	Predicate Device Volpara 1.5.2 (K153427)	Submission Device, Volpara 1.5.6
Intended Use	VolparaDensity is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. VolparaDensity 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. VolparaDensity 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.	Same as predicate.
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, including those obtained using with curved paddles.
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 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).	Volume of Fibroglandular tissue Volume of Breast Volumetric Breast Density BIRADS 4th or 5th Edition Breast Density Category, with highlighting above a certain volumetric threshold or if focal density present Average thickness of dense tissue

	Maximum volume of dense tissue above any 1cm ² square region (and location).	Maximum thickness of dense tissue (and location). Maximum volume of dense tissue above any 1cm ² square region (and location). Image quality assessment metrics
Image Output	Density map in DICOM SCI format, for visualization as user specifies.	Density map in DICOM SCI format, for visualization as user specifies
Classification	21 CFR 892.2050; LLZ	21 CFR 892.2050; LLZ
Software Level of Concern	Moderate	Moderate

Intended Use:

VolparaDensity is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. VolparaDensity 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. VolparaDensity 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 Imaging Software (“Volpara”) 1.5.6 software provides volumetric assessment of digital x-ray images of the breast, including in that definition both raw digital mammograms and raw tomosynthesis projections (the central projections of which are just raw digital mammograms).

The assessment takes the form of generating and validating density maps wherein the value at each pixel represents the thickness of fibroglandular tissue between that pixel and the x-ray source.

From the density maps various quantitative density-map based statistics are computed as follows:

- volume of fibroglandular tissue in cm³
- volume of breast in cm³,
- the volumetric breast density (the percentage of fibroglandular tissue in breast)
- average thickness of dense tissue in cm
- maximum thickness of dense tissue in cm
- maximum volume of dense tissue above any 1cm² square region (or “focal density”)

- image quality assessment metrics

From the volumetric breast density, a BI-RADS 4th Edition and 5th Edition breast density category can be attained by applying thresholds set by the software, with an increase in density category if a focal density appears to be present.

The device outputs those metrics 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 the FDA's various software guidance documents have been submitted in this Special 510(k) Notification. An ISO 14971 compliant risk analysis 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) submission, complete verification and validation data testing conducted for the predicate was repeated in order to ensure integration and backwards compatibility.

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 Special 510(k) Premarket Notification for VolparaDensity 1.5.6 contains adequate information and data to demonstrate substantial equivalence to the predicate device.
