Volpara Health Technologies Limited
℅ Ralph Highnam, Ph.D.
CEO
Level 14-15, Simpl House,
40 Mercer Street, Wellington Central
Wellington, 6011
NEW ZEALAND

July 27, 2021

Re: K211279
Trade/Device Name: Volpara Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 25, 2021
Received: July 2, 2021

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. 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,

For

Thalia T. Mills, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211279

Device Name
Volpara Imaging Software

Indications for Use *(Describe)*
Volpara Imaging Software is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara Imaging Software 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 Imaging Software provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category and quality assurance metrics (i.e., dose and pressure) to aid healthcare professionals in the assessment of breast composition. Volpara Imaging Software is not a 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Number: K211279

Volpara Imaging Software Special 510(k) Summary

Sponsor:
Volpara Health Technologies Limited

Company Address:
Level 14-15, Simpl House, 40 Mercer Street, Wellington, 6011, New Zealand

Contact Person:
Ralph Highnam

Telephone:
+64 4 499 6029

Fax:
+64 4 499 6029

Email:
ralph.highnam@volparahealth.com

Submission Date:
15 April 2021

Device Name:
Volpara Imaging Software

Common Name:
Imaging Software

Regulatory Classification:
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") 3.2 is substantially equivalent to the Volpara Imaging Software 1.5.6 cleared pursuant to K182310 (Volpara Health Technologies Limited), which serves as the primary predicate.

Predicate Device Description:
The Volpara Imaging Software 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 cm^3
- Volume of Breast in cm^3
- 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 1 cm^2 square region (and location)
- Image quality assurance 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. The device outputs those metrics along with the density maps themselves marked with the location of the various maxima. Volpara Imaging Software 1.5.6 operates on a Windows or Linux 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 3.2 is the same core software as the predicated device Volpara Imaging Software 1.5.6 with the addition of the following software and labeling updates.

The modified device is similar to the predicate, except for:

- Modified overall software architecture
- Improved combo study logic
- Ability to process Giotto Class 2D images
- Providing additional quality assurance outputs
- Improved density sanity checking
- Better support for Hologic Tomosynthesis images
- Updated user manual to include recent updates to accepted manufacturers and Intended Use statement. The minor change to the Intended Use statement is to accommodate the QA metrics (i.e., dose and pressure).

Table 1. Substantial Equivalence Comparison

	Predicate Device **Volpara Imaging Software 1.5.6 (K182310)**	**Submission Device** **Volpara Imaging Software 3.2**
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	Volpara Imaging Software[1] is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara Imaging Software calculates and quantifies a density map and from that determines volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates.

[1] Standardizing on the use of the term Volpara Imaging Software as the name of the cleared medical device. As described in previous 510(k) submissions, Volpara Imaging Software, Volpara and Volpara Density have been used interchangeably.

	Predicate Device **Volpara Imaging Software 1.5.6 (K182310)**	**Submission Device** **Volpara Imaging Software 3.2**
	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.	Volpara Imaging Software provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category and quality assurance metrics (i.e., dose and pressure) to aid healthcare professionals in the assessment of breast composition. Volpara Imaging Software is not a 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, including those obtained using with curved paddles.	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/Linux[2]	Windows/Linux
Image Storage and Report Generation	Yes; output to console	Yes; output to console
Numeric Output	• 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 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 thickness of dense tissue (and location)

[2] Volpara Imaging Software has been previously cleared for both Windows and Linux, which was missed off the 2018 submission. We are now correcting this error.

	Predicate Device **Volpara Imaging Software 1.5.6 (K182310)**	**Submission Device** **Volpara Imaging Software 3.2**
	• Maximum volume of dense tissue above any 1 cm^2 square region (and location) • Image quality assessment metrics	• Maximum volume of dense tissue above any 1 cm^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
Level of Concern	Moderate	Moderate

Intended Use:

Volpara Imaging Software is a software application intended for use with the raw data from digital breast x-ray systems, including tomosynthesis. Volpara Imaging Software 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 Imaging Software provides these numerical values along with a BI-RADS breast density 4th or 5th Edition category and quality assurance metrics (i.e., dose and pressure) to aid healthcare professionals in the assessment of breast composition. Volpara Imaging Software is not a 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:

Volpara Imaging Software 3.2 analyzes raw ("For Processing") digital mammograms or raw DBT projections in a fully automated, volumetric fashion. It produces a quantitative assessment of breast composition in the form of a Volpara density map, 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 metrics are computed as follows:

- volume of fibroglandular tissue in cm^3
- volume of breast in cm^3
- 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 1 cm^2 square region (and location)
- image quality assessment metrics

Volpara Imaging Software typically receives four standard views from the digital x-ray system following a mammographic or digital breast tomosynthesis screening examination (i.e., left CC, right CC, left MLO, right MLO). The generated results are then displayed via either of the following:

- A Volpara scorecard (a DICOM Secondary Capture Image)
- A DICOM Mammography CAD Structured Report

The device outputs those metrics along with the density maps themselves marked with the location of the various maxima. Using the volumetric breast density, a BI-RADS 4th Edition and 5th Edition breast density category is generated by applying thresholds set by the software.

Volpara Imaging Software operates on a Microsoft Azure-connected, off-the-shelf virtual appliance, which provides a secure, pre-configured virtual host. Volpara Imaging Software does not contact the patient, nor does it control any life-sustaining devices.

Performance Data:

Volpara Imaging Software has been verified and validated according to the company's design control process. All 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 is 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 2016.

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 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 Volpara Imaging Software 3.2 contains adequate information and data to demonstrate substantial equivalence to the predicate device.