K132742
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5 510(k) Summary

Prepared December 2, 2013

Submitter: VuCOMP, Inc.
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DEC 0 3 2013

Submission Date: August 30, 2013

Trade Name: M-Vu® Breast Density

Common Name: Medical Imaging Software

Classification Name: System, Image Processing, Radiological;
21 CFR 892.2050; LLZ

Device Classification: Class II

Predicate Device(s): Quantra, by Hologic Inc., K082483
Volpara, Matakina Technology Limited, K102556

Description of Device:

M-Vu Breast Density automatically analyzes "for processing" digital mammograms and calculates the dense tissue area of each breast. The measured dense tissue area is then used to provide a Calibrated Density Category which maps the percentage of breast density to a BI-RADS category number (1 – 4).

M-Vu Breast Density is a stand-alone software application designed to interoperate with all digital radiography (DR) and computed radiography (CR) mammography systems. M-Vu Breast Density is displayed in the form of a DICOM mammography structured report or secondary capture and reports the following for output:

- Breast Area (cm^2) for each breast
- Dense Area (cm^2) for each breast
- Percent Breast Density for each breast
- Breast Density Category for each case

The results of M-Vu Breast Density are designed to display on a mammography workstation, high resolution monitor, or in a printed case report. M-Vu Breast Density is designed to process approximately 60-120 cases per hour.

M-Vu Breast Density Version 1.0.0.0 has been built and tested on the M-Vu CAD Station system (K061160).

Intended Use Statement:

M-Vu Breast Density is a software application intended for use with digital mammography systems. M-Vu Breast Density calculates breast density as a ratio of fibroglandular tissue and total breast area estimates. M-Vu Breast Density provides these numerical values for each breast as well as a density category to aid radiologists in the assessment of breast tissue composition. M-Vu Breast Density produces adjunctive information. It is not an interpretive or diagnostic aid.

Summary of Technological Characteristics:

Features and Characteristics	VuCOMP M-Vu Breast Density	Predicate Devices	
		Hologic Quantra K082483	Matakina Technology Volpara K102556
Patient Population	Symptomatic and asymptomatic women undergoing mammography		
End Users	Radiologists		
Image Source Modalities	All digital radiography (DR) systems and computed radiography (CR) systems	Hologic 2D, GE 2D, and Siemens Mammomat Novation digital radiography (DR) systems only	All digital radiography (DR) systems and computed radiography (CR) systems
Input: Image Data Format	DICOM digital mammography image – For processing: Views processed: RCC, LCC, RMLO, LMLO		
Output Format	DICOM structured report and secondary capture		
Output Data	For each breast: • Area of fibroglandular tissue (cm^2) • Area of breast (cm^2) • Area-based breast density (%) For each patient: VuCOMP density grade/BIRADS breast density	For each image, breast, and patient: • Volume of fibroglandular tissue (cm^3) • Volume of breast (cm^3) • Volumetric breast density (%) • Volume of fibroglandular score • Volume of breast density score BIRADS-like breast density integer score and fractional score	For each breast: • Volume of fibroglandular tissue (cm^3) • Volume of breast (cm^3) • Volumetric breast density (%) For each patient: Volpara density grade/BIRADS breast density
Output Device	Mammography Workstation, PACS, and RIS		
Deployment	Stand-alone computer		
Data Throughput	60-120 cases per hour	30-60 cases per hour	45-60 cases per hour

Summary of Clinical Performance Data:
This submission contains no information from clinical studies.

Summary of Non-Clinical Performance Data:
M-Vu Breast Density has been verified and validated according to VuCOMP's design control processes. All supporting documentation has been included in this 510(k) Premarket Notification. Verification activity included unit, integration, and system level testing. Validation included the following:

- M-Vu Breast Density was run over a set of x-ray images for which a BI-RADS scores were obtained from 13 expert radiologists followed by a comparison of the data sets using a weighted Kappa statistic
- Estimates of fibroglandular tissue were confirmed by verifying the M-Vu percent breast density (PBD) and the M-Vu breast area. The verification of fibroglandular area measurement follows by implication.
- M-Vu Breast Density was run over a data set where the women's age and results were compared with the expected and known decrease in breast density with age using the Spearman Rank Correlation test.
- Percent Breast Density measurements from the left and right breasts of the same patient were compared to confirm that the results were similar using Pearson's Correlation Coefficient.
- Percent Breast Density measurements were made on patient images and corresponding prior images with a maximum imaging period of two years apart and the results were compared to confirm that they were similar using Pearson's Correlation Coefficient.
- M-Vu Breast Density is deployed on the M-Vu CAD Station. M-Vu CAD Station was successfully tested for clinical network integration.

Conclusion:
Based upon the information presented in this submission, it is concluded that M-Vu Breast Density is safe and effective for the intended use, and is substantially equivalent to the named predicate devices.

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 3, 2013

VuCOMP, Inc.
% Richard Morroney, RAC, CQA
Director of Quality and Regulatory Affairs
2500 Dallas Parkway, Suite 500
PLANO TX 75093

Re: K132742
Trade/Device Name: M-Vu® Breast Density
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 30, 2013
Received: October 31, 2013

Dear Mr. Morroney:

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.

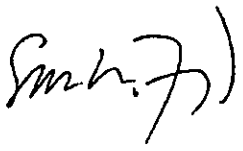
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4 Indication(s) for Use Statement

510(k) Number (if known): K132742
Device Name: M-Vu Breast Density
Indications for Use:

M-Vu Breast Density is a software application intended for use with digital mammography systems. M-Vu Breast Density calculates breast density as a ratio of fibroglandular tissue and total breast area estimates. M-Vu Breast Density provides these numerical values for each breast as well as a density category to aid radiologists in the assessment of breast tissue composition. M-Vu Breast Density produces adjunctive information. It is not an interpretive or diagnostic aid.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) ____K132742_____