PHILIPS

DEC 1 3 2013

510(k) Summary (21 CFR 807.92)

A. SUBMITTER INFORMATION

Submitter's name	Philips Digital Mammography Sweden AB
Address	Smidesvägen 5
	SE-171 41 Solna
	Sweden
Establishment registration number	3009307584
Contact person	Mr. Gustav Lins
Telephone	+46-8-623 52 00
FAX	+46-8-623 52 01
Title	Manager Regulatory Affairs
Date of the summary preparation	2013-10-09

B. DEVICE IDENTIFICATION

Device trade name	MicroDose SI (model L50)
Device common name	Full-Field Digital Mammography X-ray System
Classification name	Full-Field Digital Mammography X-ray System
Classification product code	MUE, LLZ (secondary)
Device class	II
Regulation code	21 CFR 892.1715, 21 CFR 892.2050 (secondary)

C. DEVICE DESCRIPTION

This application is to add functionality to the previously cleared MicroDose SI, Model L50, (K123995) that allows for breast density measurements.

The L50 submission described that the detector electronics have been modified to do spectral imaging through the functionality to discriminate between high and low energy photons based on an energy threshold. The first application of this technology is Spectral Breast Density Measurement where breast glandularity and thickness is measured simultaneously by the spectral difference in X-ray attenuation between adipose and fibroglandular tissue. The MicroDose SI can thereby measure volumetric glandularity and breast thickness for each pixel in the image. Total breast volume is calculated by integrating the breast thickness over the breast region, taking pixel size and beam geometry into account. Fibroglandular thickness is calculated as the product of breast thickness and volumetric glandularity for each pixel. Total fibroglandular volume is then calculated by integrating the fibroglandular thickness over the breast region. The total breast volumetric glandularity is then given as the ratio of fibroglandular to breast volume. The correlation between the MicroDose Density Score and the radiologist's BI-RADS score has The following information is sent as part of the content of a DICOM Structured Report, SR, to selected destinations (for example a PACS). Breast analysis information is also included as private attributes in the DICOM header of the acquired images.

- Volumetric glandularity (%)
- Glandular volume (cm^3)

- Breast volume (cm^3)
- Breast density score (I, II, III, IV). The density score correlates to the BI-RADS categories.

D. INDICATIONS FOR USE

The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems.

E. SUBSTANTIAL EQUIVALANCE

The subject device is identical to the MicroDose SI (model L50) in regards to FFDM characteristics. Furthermore, with regards to the applications described in this submission, it is substantially equivalent to the software predicates Volpara and Quantra.

	MicroDose SI (model L50) Subject device	MicroDose SI (model L50) K123995 Predicate	Volpara K102556 Predicate	Quantra K120472 Predicate
Manufacturer	Philips Digital Mammography Sweden AB	Philips Digital Mammography Sweden AB	Matakina Technology Limited	Hologic, Inc.
Indication For Use	The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems	The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems	Volpara is a software application intended for use with digital mammography systems. Volpara calculates volumentric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values for each image to aid radiologists in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid. Volpara is a software application which runs on Windows or Linux-based computers.	Quantra™ is a software application intended for use with images acquired using digital breast X-ray systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue area and total breast area estimates. It segregates breast density into BI-RADS-like breast composition categories, which may be useful in the reporting of consistent breast composition values for each image, breast and subject, to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information, it is not an interpretive or diagnostic aid. Quantra runs on a Windows platform.
Device Classification Name	Full field digital, System, X-ray, Mammographic	Full field digital, System, X-ray, Mammographic	System, Image Processing, Radiological	System, Image Processing, Radiological
Device Class	II	II	II	II
Detector technology	Photon counting Crystalline silicon strip detectors Rejection of electronic noise 24 x 26 cm imaging area	Photon counting Crystalline silicon strip detectors Rejection of electronic noise 24 x 26 cm imaging area	N/A	N/A
Image Evaluation Source	Digital Mammography Images		Digital Mammography Images	Digital Mammography Images
Anatomical Assessment Area	Breast	Breast	Breast	Breast

	MicroDose SI (model L50) Subject device	MicroDose SI (model L50) K123995 Predicate	Volpara K102556 Predicate	Quantra K120472 Predicate
Assessment output	Glandular volume (cm³) (volume of fibroglandular tissue)	N/A	Volume of fibroglandular tissue	Volume of fibroglandular tissue;
	Volumetric glandularity (%) (volumetric breast density)		Volumetric breast density	Volumetric breast density
	Breast volume (cm³)		Breast volume	Area breast density measure
	Breast density score (I, II, III, IV). The density score correlates to the BI-RADS categories.			BI-RADS like breast composition measure
Image storage and report generation	DICOM Structured report to send to PACS		Output to console	DICOM Structured report to send to PACS

F. PERFORMANCE/BENCH TESTING

The MicroDose SI L50 Breast Density Measurement application has been developed in accordance with Philips Digital Mammography Sweden AB's product development process. It has been verified and validated in accordance with the company's design control process. The design control process is divided into several levels of verification, unit, integration and system level. The results from the performance testing have been included in the application.

The bench testing and clinical validation of the MicroDose SI included:

- Comparisons of MicroDose Breast Density Measurement parameters to industry standard breast tissue equivalent phantoms;
- Validation that the Breast Density Measurement application can be easily incorporated into the clinical workflow of the radiologists;
- Based on a substantial clinical screening population dataset:
  - The agreement between the MicroDose Density score and the BI-RADS breast composition score given by MQSA qualified radiologists was evaluated for a screening population;
  - Evaluation of the correlation between MicroDose Breast Density Measurements in CC and MLO views and left and right laterality to confirm consistent results;
  - Evaluation of the correlation between volumetric glandularity and age to confirm the expected decrease with age;
  - Evaluation of the correlation between volumetric glandularity and breast volume to confirm the expected decrease with volume;
  - Evaluation of the correlation between volumetric glandularity and BI-RADS breast composition score to confirm the expected increase with BI-RADS score.

PHILIPS

The verification and validation activities confirm that the established acceptance criteria were met.

G. CONCLUSION

The breast density measurement functionality that is the subject of this application relies on the technology of a FFDM device which has already been cleared by the FDA (MicroDose SI, K123995). Breast density assessments have previously been introduced by Quantra (K120472) and Volpara (K102556). These devices provide information that is very similar to that generated by the MicroDose SI (Model L50), and are intended for the same purpose, i.e. to generate adjunctive information regarding breast density. Like the breast density functionality of the predicate devices Volpara and Quantra, the MicroDose Breast Density Measurement aids the clinician in the assessment of breast tissue composition. The Breast Density Measurement functionality is well characterized by the design control process and the physical laboratory tests show results that are comparative to the predicate devices.

PHILIPS DIGITAL MAMMOGRAPHY SWEDEN AB   December 13, 2013
GUSTAV LINS
MANAGER REGULATORY AFFAIRS
SMIDESVAGEN 5, SOLNA, SW SE-171 41
SWEDEN

Re: K130704
    Trade/Device Name: MicroDose SI
    Regulation Number: 21 CFR 892.1715
    Regulation Name: Full-field digital mammography system
    Regulatory Class: II
    Product Code: MUE, LLZ
    Dated: October 29, 2013
    Received: October 31, 2013

Dear Mr. Lins:

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

Indications for Use

510(k) Number *(if known)*
K130704

Device Name
MicroDose SI (Model L50)

Indications for Use *(Describe)*
The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer.

The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems.
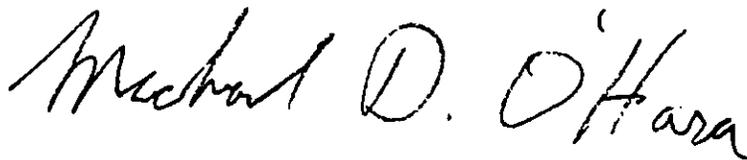

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)   ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara