SEP 2 3 2011

510(k) Summary

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems herewith submits a 510(k) Summary.

Name and Address of manufacturer:

Philips Medical Systems DMC GmbH
Roentgenstrasse 24
22335 Hamburg
Germany
Establishment Registration No.: 3003768251
Owner/Operator Number: 1217116

Name, title and phone number of official correspondent:

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Women's Health Care
Philips Healthcare
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Andover, MA 01810
Phone 978 659-7434

Device Identification:

Device Trade Name:	Philips MammoDiagnost DR
Common Name:	Full Field Mammography System

Classification of the device:

Device Classification Name:	Full Field Digital,System,X-ray,Mammographic
Product Code:	MUE
Device Classification No.:	Part 892.1715
Panel:	Radiology
Regulatory Status:	Class II

Device(s) Identification:

Device Trade Name:	Philips MammoDiagnost DR
Common Name:	Full Field Digital Mammography System

Predicate devices:

Device Trade Name:	Siemens Mammomat Novation
Applicant:	Siemens Medical Solution
510(k) No.:	P030010
Device Trade Name:	Siemens Mammomat Inspiration
Applicant:	Siemens Medical Solution
510(k) No.:	Supplement to P030010 (P030010/S6)

The Philips MammoDiagnost DR Full Field Digital Mammography System is considered substantially equivalent to Siemens Mammomat Novation and Inspiration Full Field Digital Mammography Systems. There is no significant difference in intended use or technology.

Device Description:

The Philips MammoDiagnost DR digital mammography system is designed to perform screening and diagnostic mammography procedures on standing, seated or recumbent patients. The system consists of a gantry with an operator console including the Eleva Workspot (EWS), consisting of an acquisition workstation (AWS) and a 19" touch screen monitor. The system's rotating X-ray tube (0.3 / 0.15 Focal Spot, Anode: Tungsten/Molybdenum) offers 4 anode tracks. The gantry provides motorized elevation, rapid rotation and compression via two foot switches. An operator radiation shield and a removable recessed patient face shield are included in the system as well as the following paddles: Compression paddles (7" x 9.5" & 9.5" x 12"), Axilla and Spot compression. The system is equipped with a solid state amorphous selenium detector, providing a matrix size of 3584 x 2816.

The acquisition workstation provides a high performance central processing unit with a minimum of 500GB hard disk, and a 4GB memory. A 19" flat panel touch screen color monitor on pivot mount allows the users a selectable viewing position. Acquired images are provided in DICOM MG format which allows its integration into a digital mammography environment including diagnostic review workstations, CAD Systems and PACS.

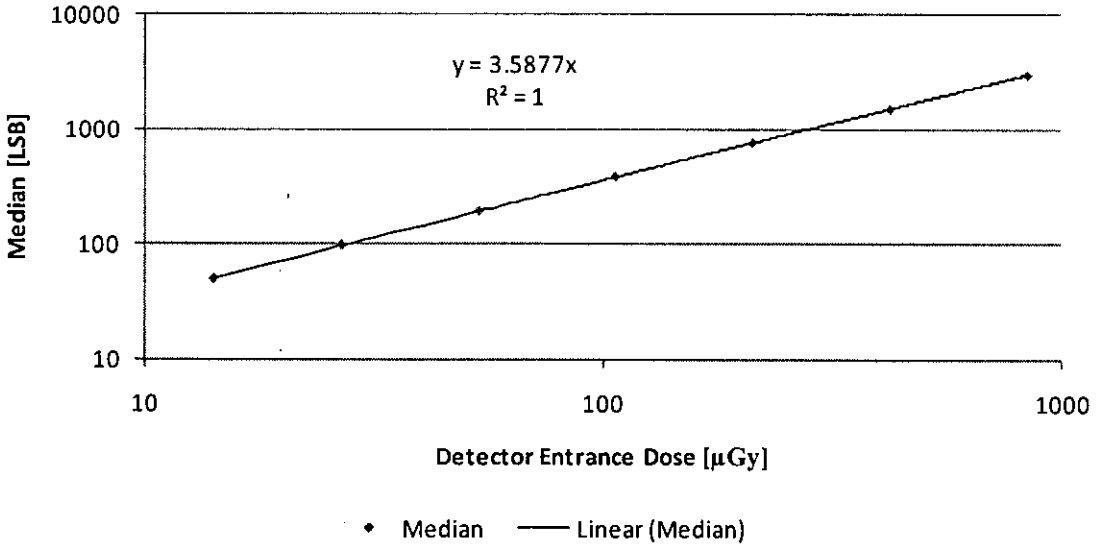
Indications for Use:

The MammoDiagnost DR is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoDiagnost DR is intended to be used in the same clinical applications as traditional film/screen systems.

Summary of Non-Clinical Performance Testing:

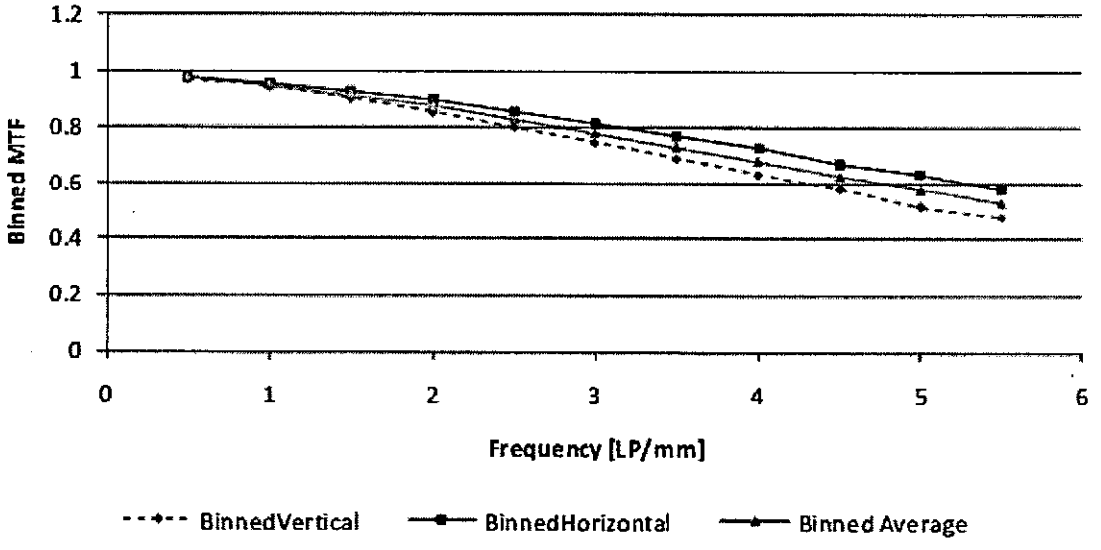
Sensitometric Response:

Sensitometric Response is a measure of the sensitivity of the image acquisition system to different levels of x-ray exposures.



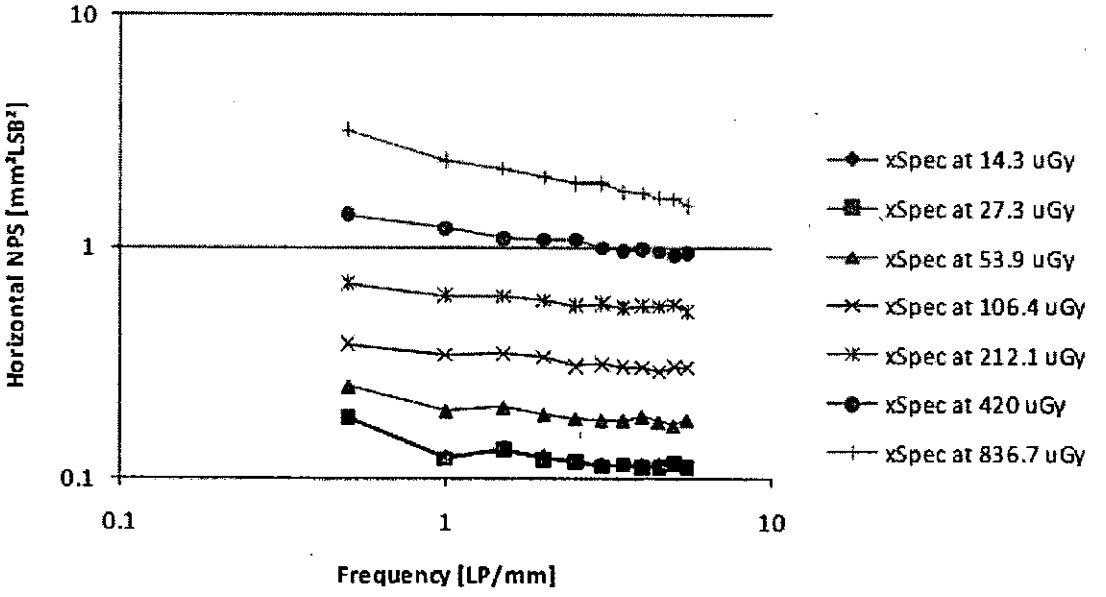
Spatial Resolution:

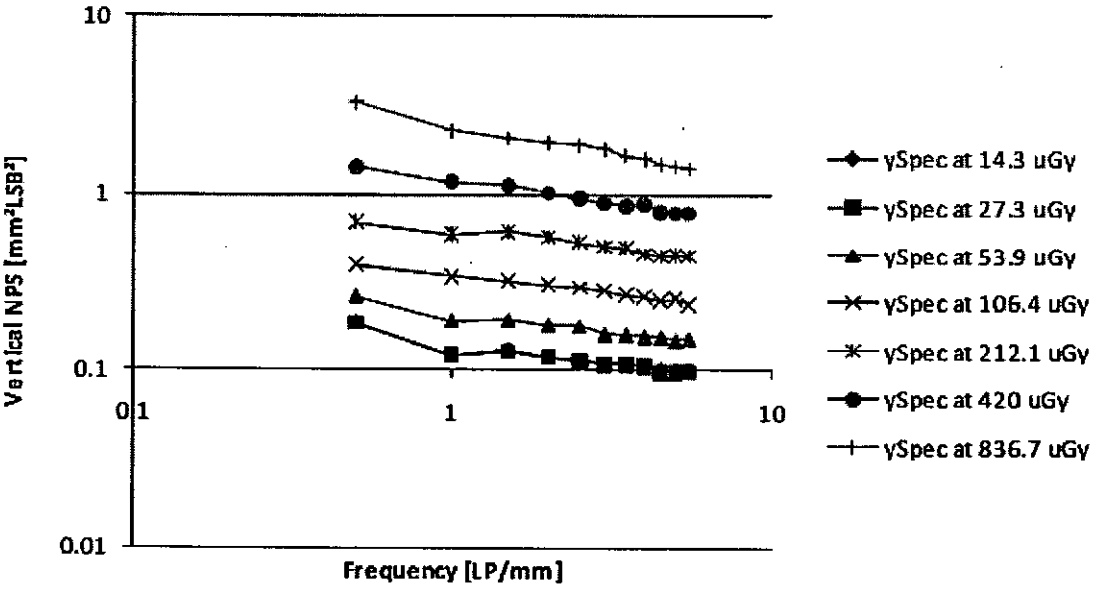
Image sharpness of an image detector can be quantified by its modulation transfer function (MTF). The spatial resolution was measured according to the IEC 62220-1-2.



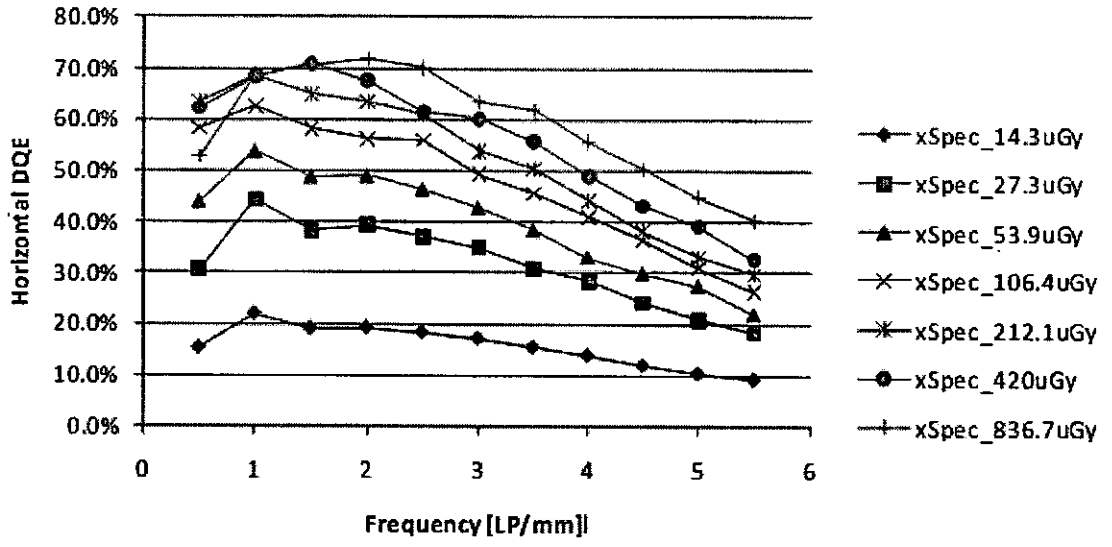
Noise Power Spectrum (NPS)

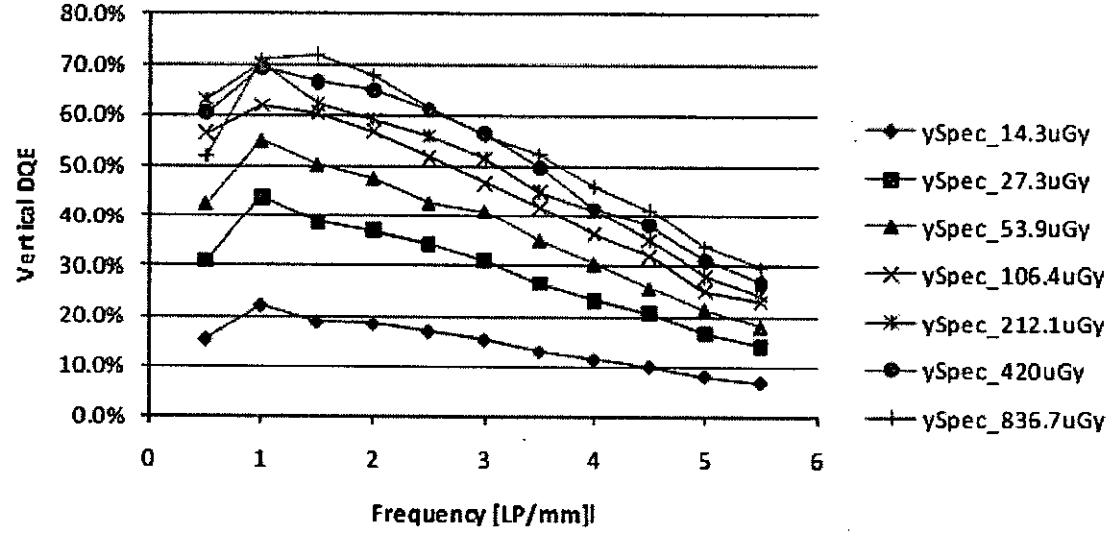
Noise power spectrum (NPS) is a characterization of the noise distribution over the spatial frequency which is an important factor contributing to image quality. The NPS (noise power spectra) was measured at 8 dose levels, and was calculated according to the IEC 62220-1-2.





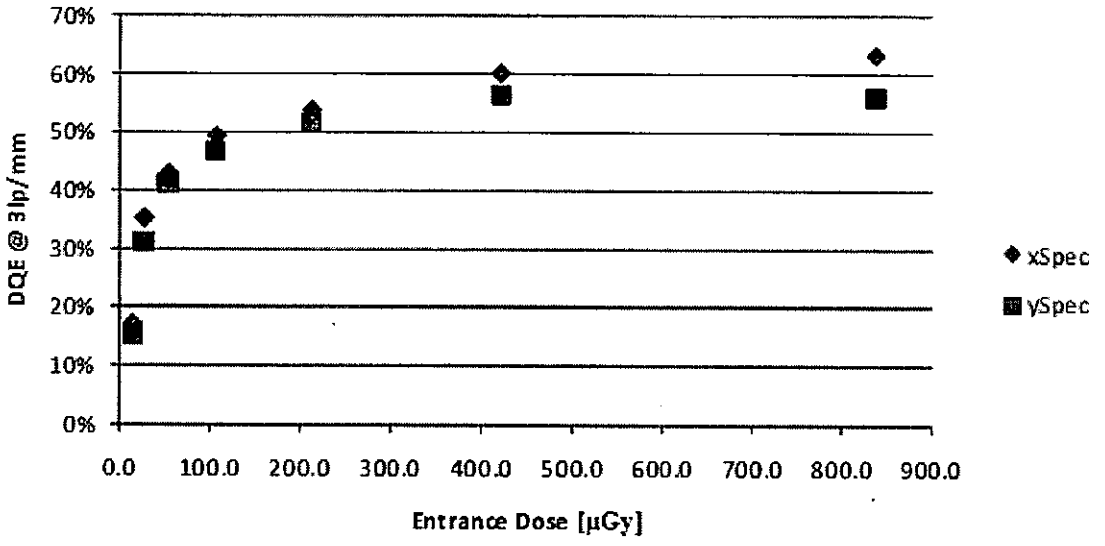
Signal-to-Noise Ratio (SNR):
The efficiency of SNR transfer of the image acquisition system is measured by the DQE (detective quantum efficiency) as a function of spatial frequency. DQE provides a measure of the combined effect of the noise and contrast performance of an imaging system, expressed as a function of object detail. The DQE was measured according to the IEC 62220-1-2.





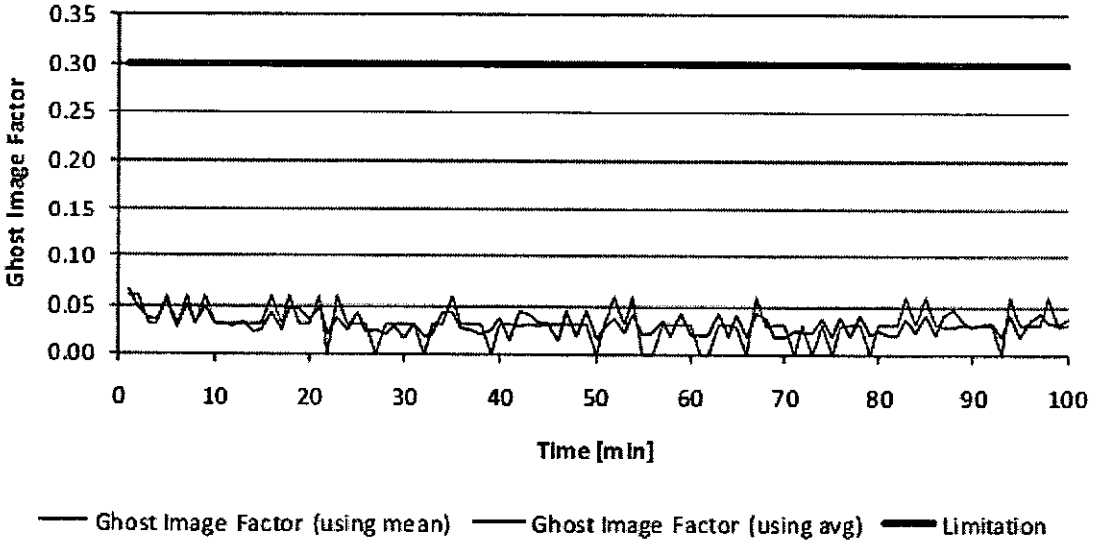
Dynamic Range

Dynamic range is a measure of the signal response of a detector exposed to x-rays. The dynamic range was characterized by plotting the DQE over dose at low and mid frequencies.



Repeated Exposure Test

The purpose of this measurement is to qualify the lag behavior of the digital x-ray detector. The measurement was repeated 100 times, the time period between each image was set to one minute.



Phantom Image Tests

Image quality is also demonstrated by analysis of phantom images. Philips evaluated the visibility of various features of the American College of Radiology (ACR) accreditation phantom

and the CDMAM contrast-detail mammography phantom. Scoring of the ACR phantom and analysis of the CDMAM phantom images were used to assess the MammoDiagnost DR image quality. CDMAM image acquisition and analysis were performed following EUREF guidelines (Bosmans H et al., 2009) and the published scientific literature (Young KC et al., 2008). The table below presents the results for normal and high dose using a 4 mm thickness ACR MAP phantom. Both phantom tests demonstrate the excellent detection capabilities of the MammoDiagnost DR System.

Softcopy									
Mode	Fibers	Artifacts	Score	Speck Groups	Artifacts	Score	Masses	Artifacts	Score
Normal Dose	5.5	0	5.5	4.0	0	4.0	4.0	0	4.0
High Dose	6.0	0	6.0	4.0	0	4.0	4.0	0	4.0
Hardcopy									
Mode	Fibers	Artifacts	Score	Speck Groups	Artifacts	Score	Masses	Artifacts	Score
Normal Dose	5.5	0	5.5	4.0	0	4.0	4.0	0	4.0
High Dose	6.0	0	6.0	4.0	0	4.0	4.0	0	4.0

Automatic Exposure Control (AEC)
Automatic exposure control (AEC) is a technology that is widely used in standard x-ray imaging and digital imaging systems. The objective of an AEC system is to optimize image quality while minimizing patient dose in an effort to produce consistent radiology images. The performance of the AEC was evaluated by acquiring data sets of varying breast equivalent thicknesses in both normal and high dose modes. An Aluminum target of 0.2 mm was used for the CNR measurement. CNR in both normal and high dose contact modes changed by less than 10% per centimeter of PMMA thickness.

Patient Radiation Dose
Breast equivalent phantom blocks were used to simulate fibroglandular/adipose tissue composition. Phantom thicknesses of 2 cm, 4 cm, and 6 cm were tested. For each phantom the system AEC was used to select x-ray exposure parameters. Results for the 50/50 fibroglandular/adipose tissue composition in contact mode are given in the table below.

Thickness (cm)	mAs	kV	Target	Filter	Entrance exposure (mR)	Mean Glandular Dose (mGy)
2	35.2	25	W	Rh	98.1	0.44
4	86.7	26	W	Rh	289.9	0.87
6	194.3	28	W	Rh	854.0	1.91

Summary of Clinical Image Evaluation:

In accordance to the Class II Special Controls Guidance Document: Full-Field Digital Mammography System, an image attribute review was completed on 6 mammographic image cases that were acquired from the Philips FFDM system, MammoDiagnost DR. The purpose of the image attribute review was to determine if images from the Philips FFDM device had acceptable quality for mammographic screening and diagnostic usage and were substantially equivalent to a predicate device as determined by a MQSA review of the investigational FFDM images.

Six screening and diagnostic mammography cases consisting of 4 standard views (RCC, RMLO, LCC, LMLO) including magnification or spot views from the diagnostic cases were reviewed by two expert Radiologist's meeting the radiologists' qualifications specified in the Class II Special Controls Guidance Document: Full-Field Digital Mammography System. The mammography cases were acquired from non-pregnant women over the age of 40. Women with breast implants were not included in the study.

The image sets for this evaluation were reviewed in the same manner as clinical images submitted by a mammography facility for MQSA accreditation. The reviewers evaluated the mammographic attributes for each case, scored the attributes with a 1 (worse)-5 (best) score and determined an overall pass/fail for each case. The two expert breast imaging subspecialist radiologists agreed that the six image sets from the Philips MammoDiagnost DR system are of sufficiently acceptable quality for clinical mammographic usage.

Substantial Equivalence Discussion:
The Philips MammoDiagnost DR Full Field Digital Mammography System is considered substantially equivalent to Siemens Mammomat Novation and Inspiration Full Field Digital Mammography Systems. The MammoDiagnost DR has the same intended use and indications for use as the predicate devices. In addition there is no significant difference in technology. Like the predicate Inspiration System, the MammoDiagnost has an X-ray system with 0.3 / 0.15 Focal Spots and Tungsten/Molybdenum anodes, Rhodium//Molybdenum filters. Both systems use a solid state amorphous selenium detector with a matrix size of 3584 x 2816. The image quality performance characterized by DQE and MTF are very similar.

Conclusion:
Philips believes that the Philips MammoDiagnost DR Full Field Digital Mammography System is substantially equivalent to the currently legally marketed devices. It has the same intended use, does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Linda Jalbert
Director, Quality and Regulatory
Philips Medical Systems
3000 Minuteman Road
ANDOVER MA 01845

SEP 23 2011

Re: K110572
Trade/Device Name: Philips MammoDiagnostic DR
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field mammography system
Regulatory Class: II
Product Code: MUE
Dated: August 15, 2011
Received: August 16, 2011

Dear Ms. Jalbert:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known):

Device Name: Philips MammoDiagnost DR

Indications For Use: The Philips MammoDiagnost DR is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoDiagnost DR is intended to be used in the same clinical applications as traditional film/screen systems.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110572