K111324

DEC 2 2 2011

510(K) SUMMARY: AGFA DX-M

Common/Classification Name: 21CFR 892.1715 and 21CFR892.1650
Proprietary Name: CR Mammography System with DX-M Digitizer
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: May 6, 2011
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(K) for Agfa's CR Mammography System with DX-M Digitizer, a detector-only FFDM system. It is substantially equivalent to Fujifilm Medical Systems' Fuji Computed Radiography Mammography Suite (FCRm).

B. DEVICE DESCRIPTION

The new device is defined as:

- Agfa's DX-M digitizer,
- HM5.0 image detectors designed for mammography, and
- The NX user workstation with a mammography license.

The device uses detectors which are exposed to x-rays. The detectors are then scanned by the digitizer to create an electronic image. The images are sent to a user workstation for patient identification, image previewing and adjustment, before sending them to a viewing workstation (PACS system) or printer for use by the physician. Principles of operation and technological characteristics of the new and predicate devices are the same. With optional general radiography screens and cassettes, the DX-M digitizer has the same capabilities as Agfa's DX-G.

C. INTENDED USE

Agfa's CR Mammography System with DX-M Digitizer is indicated for use in diagnostic and screening mammography. It is intended to be used wherever conventional film/ mammography screen systems are used.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's CR Mammography System with DX-M Digitizer has an Indications For Use statement nearly identical to the statement for the predicate device (Fuji FCRm). Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE		
	NEW DEVICE **Agfa CR Mammography System with DX-M Digitizer**	**Predicate - PA05014** **Fuji Computed Radiography for Mammography, FCR*m***
Indications	Same as the predicate	Mammography
Communications	Same as the predicate	DICOM
Detector Material	CsBr:Eu2+	$BaFBr_{1-x}I_x:Eu^{2+}$
Detector Sizes	Same as the predicate	18x24 cm 24x30 cm
Pixel Matrix	HM5.0: 18x24 cm – 3508x4644 24x30 cm – 4708x5844	HR-BD: 18x24 cm – 3450x4740 24x30 cm – 4728x5928
Scanning resolutions	50µ	50µ
Acquisition Gray Scale (Bit Depth)	16 bit sq. root compression	12 bit logarithmic compression
Displayed Image File Gray Scale	12 bit	12 bit
Maximum Image Acquisitions/hr.	41 (mammo, 24x30)	65/hr - Profect CS (24x30) 40/hr - Profect One (24x30)
Dimensions and Weight	43.5x20x48.4 in. 397 lb.	Profect CS • 26x29x58 in. • 628 lb. Profect One • 26x29x52 in. • 529 lb.
Image processing	MUSICA^2 for Mammography with Micro Calcification Enhancement (MCE)	Dynamic Range Control/Multi-Frequency Processing (DRC/MFP) Pattern Enhancement for Mammography (PEM)
X-ray System	Same as the predicate	Legally on the market, Designed specifically for mammography
Softcopy Display	Same as the predicate	Legally on the market for mammography
Hardcopy Output	Same as the predicate	Legally on the market for mammography
Electrical Safety	Same as the predicate	IEC-60601-1

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's CR Mammography System with DX-M Digitizer consists of:

- Mammography detectors containing phosphor coated image plates that capture the patient image.
- A digitizer which scans the detector and extract the image.
- A NX workstation to identify the patient, preview and adjust the image, then direct the image to where it is needed.

F. TESTING

The new device includes proven technology from the other Agfa computed radiography systems which has been tested to demonstrate its suitability for digital mammography.

The device has been shown to conform to the electronic medical product safety, radiology, and medical imaging standards: IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 62220-1-2, IEC 61223-2-3 and ACR/NEMA PS3.1–3.18 (DICOM). The following management standards have also been applied: ISO 13485, ISO 14971.

Laboratory imaging tests of the new device consistent with IEC 62220-1-2 has been completed. Laboratory tests considered sensitometric response, spatial resolution, noise analysis, dynamic range, erasure, fading, repeat exposures, AEC performance and an evaluation of images from mammography phantoms. Comparisons to the predicate device followed FDA guidance. Test results demonstrated performance equivalent or better than the predicate device.

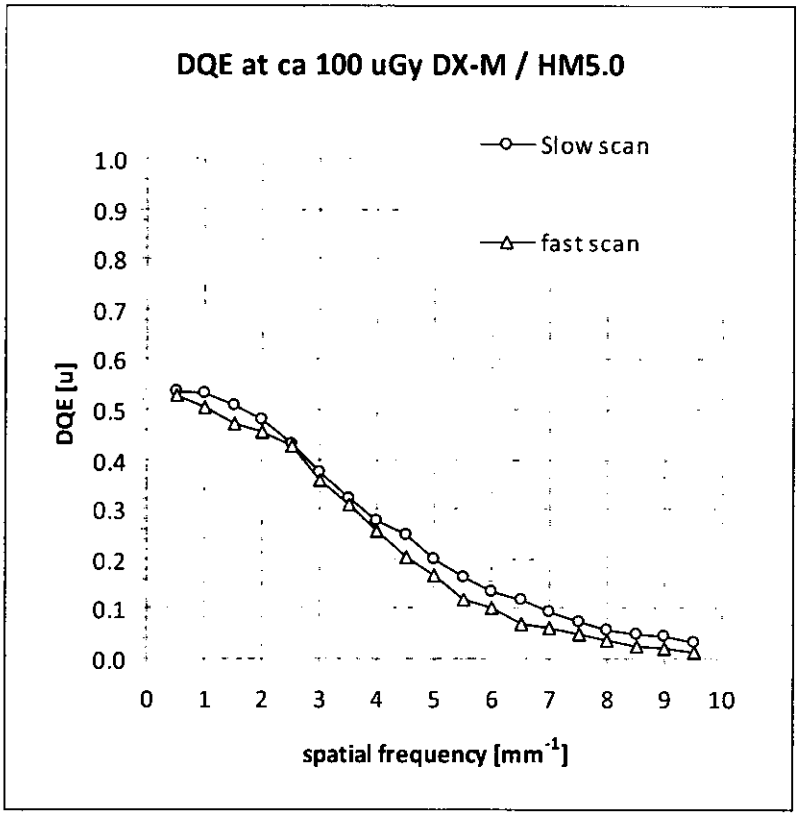

Figure 1 DQE data at ca. 100 µGy exposure level.

An evaluation of clinical images by expert, MQSA qualified radiologists was conducted. Reviewers evaluated breast positioning, exposure, image contrast, sharpness, tissue visibility at the skin line noise and overall clinical image quality. Anonymized images were evaluated to determine if they were of acceptable quality for mammographic use. Reviewers found all studies to be of acceptable overall clinical image quality.

Development of the new device did not involve patient exposures or treatment.

G. CONCLUSIONS

This 510(K) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 2 2011

Agfa HealthCare N.V.
% Mr. Phil Cuscuna
Regional Regulatory Affairs & QS Manager
Agfa HealthCare Corp.
10 South Academy Street
GREENVILLE SC 29601

Re: K111324
Trade/Device Name: Agfa's CR Mammography System with DX-M digitizer
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: October 17, 2011
Received: October 19, 2011

Dear Mr. Cuscuna:

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

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: CR Mammography System with DX-M Digitizer

Indications for Use:

Agfa's CR Mammography System with DX-M Digitizer is indicated for use in diagnostic and screening mammography. It is intended to be used wherever conventional film/screen mammography systems are used.

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 CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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