K121095



AUG 16 2012

# 5. 510(K) Summary

**510(K) SUMMARY: AGFA DX-D Imaging Package**

Regulation Name: Image Intensified fluoroscopic x-ray system (21 CFR 892.1650)
Classification Name: Solid state x-ray imager (flat panel/digital imager) (product code MQB)
Common Name: Direct radiography system
Proprietary Name: DX-D Imaging Package
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: January 15, 2012
Telephone: (416) 240-7317
Facsimile: (416) 240-7359

## A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for the latest version of Agfa's DX-D Imaging Package, a solid state, flat-panel x-ray imaging system.

## B. DEVICE DESCRIPTION

The device is a direct radiography imaging system of similar design and construction to the predicate. Agfa's DX-D Imaging Package uses the company's familiar NX workstation with MUSICA$^2$ ™ image processing and flat panel detectors of the scintillator-photodetector type. Flat panel detectors with scintillators of both Cesium Iodide (CsI) and Gadolinium Oxysulfide (GOS) are available. The device is used to capture and directly digitize x-ray images without a separate digitizer common to computed radiography systems. This new version uses a previously cleared detector with wireless communication capability.

The device uses a direct conversion process to convert x-rays into a digital signal. X-rays incident on the scintillator layer of the detector generate light that is absorbed by photo-detectors, converted to a digital signal and sent to the workstation. At the workstation the data is processed by Agfa's MUSICA$^2$ image processing software. The acronym MUSICA stands for **Mu**lti-Stage-**I**mage-**C**ontrast-**A**mplification. MUSICA$^2$ acts on the acquired images to preferentially enhance the diagnostically relevant, moderate and subtle contrasts.

Principles of operation and technological characteristics of the new and predicate devices are the same.

## C. INTENDED USE

Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The

DX-D Imaging Package may be used wherever conventional screen-film systems may be used.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D Imaging Package has an Indications For Use statement similar to the statements for the predicate device, K092669. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

The device does not have therapeutic effects. Differences in new device and the predicate do not alter the intended diagnostic effect.

PRODUCT COMPARISON TABLE

| | **DX-D Imaging Package (New Device)** | **AGFA DX-D Imaging Package (PREDICATE-K092669)** |
|---|---|---|
| **Communications** | DICOM | DICOM |
| **Flat Panel Manufacturer** | Varian Medical Systems (wired detectors)<br>Canon (wireless detector) | Varian Medical Systems |
| **Detector Material** | Varian: Gadolinium Oxysulfide (GOS), or<br>Varian & Canon: Cesium Iodide (CSI) | Gadolinium Oxysulfide (GOS) or<br>Cesium Iodide (CSI) scintillator |
| **Detector Sizes** | 17x17 in.<br>14x17 in. | 17x17 in.<br>14x17 in. |
| **Active Matrix (14x17 in.)** | 2560x3072 (Varian)<br>2800x3408 (Canon) | 2560x3072 |
| **Pixel size** | 139 µm (Varian), or<br>125 µm (Canon) | 139 µm |
| **Dynamic Range** | 14 bit | 14 bit |
| **Maximum Image Acquisitions/hr.** | 150 | 150 |
| **Power Supply** | 47-63 Hz<br>90-264V auto ranging | 47-63 Hz<br>90-264V auto ranging |
| **Operator Workstation** | Agfa NX | Agfa NX |
| **Image processing** | MUSICA$^2$ | MUSICA$^2$ |
| **Operating system** | Windows 7 | Windows XP Pro |
| **Display System** | Standard PC display or separately cleared medical display (e.g. K051901) | Standard PC display or separately cleared medical display (e.g. K051901) |

## E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D Imaging Package is a scintillator-photodetector type solid state x-ray imaging system. The device provides the user with a choice of three wired or wireless flat panel detectors to capture and digitized the image. A computer workstation allows users view and process images, and forward them to other devices (e.g. a PACS or printer).

The DX-D Imaging Package is integrated with compatible x-ray systems.

## F. TESTING

Image quality measurements have been completed. Image quality comparisons between the new and predicate devices have been performed as well. Sample images have been provided.

Performance of the complete system has been validated.

No clinical testing was performed in the development of the DX-D Imaging Package.

The product, manufacturing and development processes have been shown to conform to product safety, radiology, and imaging standards including:

**PRODUCT STANDARDS**

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, plus collateral standard: Electromagnetic compatibility - requirements and tests.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ACR/NEMA PS3.1-3.18: Digital Imaging and Communications in Medicine (DICOM)

**MANAGEMENT STANDARDS**

- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

## 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

AUG 16 2012

Agfa Healthcare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K121095
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 24, 2012
Received: April 25, 2012

Dear Mr. Job:

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121095

# Indications for Use Form

510(k) Number (if known): _____

Device Name: DX-D Imaging Package

**Indications for Use:**

Agfa's DX-D Imaging Package is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package may be used wherever conventional screen-film systems may be used.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

| | | |
|---|---|---|
| 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

510(k) K121095