MAR 1 1 2013

K122736
Page 1 of 4

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

Common/Classification Name: Stationary X-ray System, 21 CFR 892.1680
Proprietary Name: DX-D Imaging Package
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: September 4, 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 original (predicate) version of the device. 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. This new version includes optional image processing algorithms for adult, pediatric and neonatal images that were previously cleared for use in Agfa's computed radiography systems.

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 for adult, pediatric and neonatal examinations. The DX-D Imaging Package may be used wherever conventional screen-film systems, CR or DR 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 devices, K090672 and K092669. Intended uses are the same. The devices have the same technological characteristics.

The new device is physically equivalent to the previous version, K092669 but includes the optional image processing settings utilized in the computed radiography predicate, K090672. Performance data including laboratory image quality measurements and image comparison studies by independent radiologists are adequate to ensure equivalence.

Differences in devices do not alter the intended diagnostic effect.

PRODUCT COMPARISON TABLE			
	DX-D Imaging Package (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K092669)**	**AGFA CR Systems with NX Workstations (PREDICATE-K090672)**
Communications	Same as predicates	DICOM	DICOM
Flat Panel or Image Plate	Same as K092669	Flat Panel Detector	Image Plates with Cassettes
Detector Material	Same as K092669	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CSI) scintillator	HD5.0 (CsBr:Eu) MD4.0 (BaSrFBrI:Eu)
Detector Sizes	Same as K092669	17x17 in. 14x17 in.	14x17 in. 14x14in. 8x10 in. 10x12 in
Active Matrix (14x17 in.)	Same as K092669	2560x3072	3408 x 4200 (HD5.0) 2320 x 2832 (MD4.0)
Pixel size	Same as K092669	139 µm	100 µm
Dynamic Range	Same as K092669	14 bit	12 bit
Maximum Image Acquisitions/hr.	Same as K092669	150	100
Power Supply	Same as predicates	50-60 Hz 100-240V auto ranging	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as predicates	Agfa NX	Agfa NX
Image processing	Same as K090672	MUSICA^2	MUSICA^2, MUSICA^2 Platinum MUSICA^2 Neonatal
Operating system	Windows 7	Windows XP Pro	Windows XP Pro
Display System	Same as predicates	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 NX workstation allows users to view and processes 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 measurement data has been provided. In-hospital image quality comparisons have been conducted with qualified independent radiologists as well. Sample images have been

provided.

Performance of the complete system has been validated.

The product, manufacturing and development processes conform to product safety and medical 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 Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Agfa Healthcare, N.V.
% Mr. David Ledwig
Principal Consultant
Practical Compliance, LLC
P.O. Box 1927
BREVARD, NC 28712

Re: K122736
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: February 08, 2013
Received: February 12, 2013

Dear Mr. Ledwig:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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): K122736

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 for adult, pediatric and neonatal examinations. The DX-D Imaging Package may be used wherever conventional screen-film systems, CR or DR 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 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k): K122736