JAN - 3 2010

510(K) SUMMARY: AGFA DX-D 100

Common/Classification Name: Mobile X-Ray System, 21 CFR 892.1720
Proprietary Name: DX-D 100
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: October 29, 2010
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D 100, which is a combination of a mobile x-ray system and a digital detector.

B. DEVICE DESCRIPTION

The new device is a combination of a conventional mobile x-ray system with digital image capture equipment. The new device is essentially a modification of the predicate mobile x-ray system, Sedecal Easy Moving Plus (K090322). In this case, the digital detector available with the predicate has been replaced with Agfa's system, its previously cleared DX-D Imaging Package (K092669). The DX-D 100 uses Agfa's familiar NX workstation with MUSICA^{2}™ image processing and flat panel detectors of the scintillator-photodetector type (Cesium Iodide or Gadolinium Oxysulfide).

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

C. INTENDED USE

Agfa's DX-D 100 is indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

Systems can be used with MUSICA^{2} image processing to create radiographic images of the skeleton including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D 100 is not indicated for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D 100 has an Indications For Use statement nearly identical to the statements for the two predicate devices (Agfa DX-D Imaging Package and the Sedecal Easy Moving Plus). 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			
	AGFA DX-D 100 (NEW DEVICE)	AGFA DX-D Imaging Package (PREDICATE - K092669)	Sedecal Easy Moving Plus (PREDICATE - K090322)
Communications	Same as predicate	DICOM	N/A
Detector Material	Same as predicate	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CSI) scintillator	N/A
Detector Sizes	Same as predicate	14x17 in. & 17x17 in	N/A
Active Matrix	Same as predicate	3056x3056 (17x17 in.) 3072x2560 (17x14 in.)	N/A
Pixel size	Same as predicate	139 µm	N/A
Fill factor	Same as predicate	100%	N/A
Dynamic Range	Same as predicate	14 bit	N/A
Maximum Image Acquisitions/hr.	Same as predicate	150	N/A
Image processing	Same as predicate	MUSICA^2	N/A
Operating system	Same as predicate	Windows XP	Windows XP
Image Acquisition	Agfa DX-D Imaging Package	Agfa DX-D Imaging Package	Canon 50G
Display System	15" LCD touch screen	Standard PC display or separately cleared medical display (e.g. K051901)	15" LCD touch screen
Configurations	Same as predicate	N/A	Battery operated mobile x-ray system
Electrical Safety	Same as predicate	IEC-60601	IEC-60601
Performance Standard	Same as predicate	N/A	21CFR1020.30
Generators	Same as predicate	N/A	Choice of four models, 20-50 kW
Collimator	Same as predicate	N/A	Ralco 221 (manual)

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D 100 includes both a mobile x-ray system for patient exposure and digital image capture equipment.

The x-ray system components of each device will include one of four generators (20-50 kW) and one of four x-ray tubes (Toshiba 140 – 300 KHU) on a battery powered cart that allows the device to be easily positioned wherever the patient is located (e.g.: emergency or acute care locations).

Each device also includes a flat panel digital detector of either Cesium Iodide or Gadolinium Phosphate (CsI or GOS) and Agfa's NX computer workstation for previewing and processing the digital image.

F. TESTING

The new device combines proven technology from both predicates which have been combined to create the new device. The new device includes minor modifications that have been fully tested.

The device has been tested and shown to conform to electronic medical product safety, radiology, and medical imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1-1: 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)
- IEC 60601-1-3: Medical electrical equipment – Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-7 (1998-02) Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-28 Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-32 Particular Requirements For The Safety Of Associated Equipment Of X-Ray Equipment

MANAGEMENT STANDARDS

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

Performance of the complete system has been validated. Sample images have been provided.

No clinical testing was performed in the development of the DX-D 100.

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

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

JAN - 3 2010

Re: K103597
Trade/Device Name: DX-D 100
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: December 7, 2010
Received: December 8, 2010

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 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

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,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

JAN - 3 2010

510(k) Number (if known): K103597

Device Name: DX-D 100

Indications for Use:

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Systems can be used with MUSICA^2 image processing to create radiographic images of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D 100 is not indicated for use in mammography.

Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(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) K103597