K092238

510(K) SUMMARY AGFA COMPUTED RADIOGRAPHY (CR) SYSTEMS WITH DX-G DIGITIZERS

Common/Classification Name: Computed Radiography System, 21 CFR 892.1650
Proprietary Name: Computed Radiography (CR) Systems With DX-G Digitizers
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jeffery A. Jedlicka, Prepared: July 13, 2009
Telephone: (864) 421-1815
Facsimile: (864) 421-1635

AUG 11 2009

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Computed Radiography Systems with DX-G Digitizers. The predicate devices are Agfa's Computed Radiography Systems with NX Workstations (K090672).

B. DEVICE DESCRIPTION

The new devices are computed radiography imaging systems of similar design and construction to the predicates. The devices capture radiographic exposures on phosphor plates that are then scanned with a laser to create an electronic image. Electronic images can then be manipulated, printed, or sent to a softcopy capable display or archive such as a PACS system.

New DX-G digitizers provide the following new benefits:

- The ability to use both standard and needle phosphor image plates with a single digitizer.
- Input and output cassette storage buffers that allow the x-ray technologist to load up to five exposed cassettes at a time. The cassettes can be of any type and size, freeing the technologist from having to process and wait on each image separately.
- An image data format that provides slightly improved latitude for over-exposures.

The principles of operation of the new and predicate devices are the same. They have the same underlying technological characteristics.

C. INTENDED USE

Agfa's Computed Radiography Systems with DX-G Digitizers have the same intended use as the predicate devices:

They are intended for use in providing diagnostic quality images to aid the physician with diagnosis.

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

System options and accessories are available for:

- Pediatric imaging
- Full leg/full spine
- Radiotherapy planning and QC
- Musica^2 Platinum (thorax, abdomen or musculoskeletal regions of adult or pediatric patients)
- Musica^2 Neonatal

In the USA, Agfa's Computed Radiography Systems with DX-G Digitizers are not intended for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Computed Radiography (CR) Systems with DX-G Digitizers have the same indications for use statement as the legally marketed predicate devices (those with NX software). 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.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices. Both the predicate and new devices use x-rays received by photostimulable plates to create latent diagnostic images. Plates are then scanned by a laser which converts the images into a digital form that can be previewed, adjusted if necessary, then stored locally, sent to an archive, printed or sent to a softcopy capable display such as a PACS system.

F. TESTING

Agfa's Computed Radiography (CR) Systems with DX-G Digitizers have been tested for proper performance to specifications through various internal tests. Components have been tested and shown to meet the requirements of EN 60601-1-1 and EN 60601-1-2.

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 Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 23 2013

Re: K092238
Trade/Device Name: Computed Radiography (CR) Systems with DX-G Digitizers
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 22, 2009
Received: July 23, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 11, 2009.

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

Indications for Use

510(k) Number (if known): K092238

Device Name: **Computed Radiography (CR) Systems with DX-G Digitizers**

Indications for Use:

Agfa's Computed Radiography Systems with DX-G Digitizers are indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

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

System options and accessories are available for:

- Pediatric imaging
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Agfa's Computed Radiography Systems with NX Workstations are not indicated for use in mammography.

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 OF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092238

Concurrence of CDRH, Office of Device Evaluation (ODE)