K081963

 JUL 25 2008

## 510(k) Summary DX-Si

Common/Classification Name: Computed Radiography, 21 CFR 892.1650
Proprietary Name: Computed Radiography (CR) Systems with NX 2008 Workstations

Agfa HealthCare Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Jeffery A. Jedlicka, Prepared: May 6, 2008
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### A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's computed Radiography Systems with NX 2008 Workstations. The predicate devices are Agfa's Computed Radiography Systems with NX2.0 Workstations (K071162).

### B. DEVICE DESCRIPTION

The predicate and new devices are nearly identical computed radiography imaging systems. NX 2008 systems (new devices) have updated hardware and software that offers:

- An optional medical grade display. The display is cleared separately by the display manufacturer.
- The capability to operate as a mixed-use system for both general radiography and mammography (where approved or licensed). This is not the case for the USA the separately licensed mammography system is not available.
- Improved tools for installation, configuration and management.
- The ability to receive DICOM veterinary images and data.

The basic 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 NX 2008 software are indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

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

When used with separately cleared accessories the systems can be conveniently used to generate urological, tomographic, pediatric and dental images, and for radiotherapy planning and quality control.

When used with Musica$^2$ Platinum software the systems are indicated for creating high quality images of the thorax, abdomen or musculoskeletal regions of adult or pediatric patients.

Agfa's Computed Radiography Systems with NX 2008 software are not indicated for use in mammography.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

These Computed Radiography (CR) Systems With NX 2008 Workstations have the same indications for use statement as the legally marketed predicate devices (those with NX2.0 software).

The intended uses of the new and predicate devices are highly similar.

- Users of the new device have the ability to purchase the device with a separately cleared medical grade display instead of reading images only on other (external) medical displays, or on films.
- The system can operate in a mixed-use mode for general radiography and mammography (not in the USA).
- The ability to receive and transmit DICOM veterinary images.
- The user interface and system documentation are available in a number of additional languages.
- Installation, configuration and management of the system is simplified

Digitizers and cassettes are unchanged from the predicates.

The differences 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 diode array 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 NX2008 Workstations 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. No clinical testing was involved

## 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
Silver Spring, MD 20993

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

MAY - 7 2012

Re: K081963
Trade/Device Name: Computed Radiography (CR) Systems with NX 2008
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 9, 2008
Received: July 10, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of July 25, 2008.

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): _____

Device Name: **Computed Radiography (CR) Systems with NX 2008**

Indications for Use:

Agfa's Computed Radiography Systems with NX 2008 software are indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

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

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Agfa's Computed Radiography Systems with NX 2008 software are 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081963