 K063421

510(k) Summary DX-Si

Common/Classification Name: Computed Radiography, 21 CFR 892.1650

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

Contact: Jeffery A. Jedlicka, Prepared: October 6, 2006

NOV 2 2 2006

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-Si integrated digital imaging system. The DX-Si is a combination of Agfa's DX-S digitizer with NX workstation and an x-ray system manufactured by Siemens Medical Solutions, AG.

The predicate devices are Agfa's Computed Radiography System DX-S with NX workstation which was cleaned by FDA on January 17, 2006 (K053634) and Siemens Multix Top x-ray system (K971452, K010571), last cleared by FDA on March 28,2001

B. DEVICE DESCRIPTION

The predicate and new devices are nearly identical computed radiography imaging systems. The DX-Si (new device) is a combination of previously cleared systems combined and marketed as a single system. The devices are the DX-S Digitizer with NX workstation and Siemens OEM version of its Multix Top x-ray system.

The new device includes an interface that allows users to select initial x-ray exposure settings and review exposure parameters from the digitizer workstation.

The basic principles of operation are unchanged.

C. INTENDED USE

Agfa's DX-Si integrated digital imaging system is intended for use in providing diagnostic quality images to aid the physician with diagnosis. The DX-Si can be used to perform radiographic exposures of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Separately cleared accessories allow the DX-Si to be conveniently used in generating pediatric, dental, urological and tomographic images.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-Si integrated digital imaging system has the same indications for use as the legally marketed predicate devices, so the first decision

point in the 510(k) Decision Algorithm is straight-forward. They have the same technological characteristics as the predicate device. This premarket notification has described the characteristics of the devices in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices.

F. TESTING

The DX-Si integrated digital imaging system has been tested for proper performance to specifications through various in-house and imaging performance tests. All 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 Corporation
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

AUG 23 2013

Re: K063421
Trade/Device Name: DX-Si
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: November 6, 2006
Received: November 13, 2006

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of November 22, 2006.

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): 063421

Device Name: DX-Si

Indications for Use:

Agfa's DX-Si system is indicated for use in providing diagnostic quality images to aid the physician with diagnosis. The DX-Si can be used to perform radiographic exposures of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts. The DS-Xi is not indicated for use in mammography.

Use with separately cleared accessories allows the DX-Si to be conveniently used in generating urological, tomographic, pediatric and dental images.

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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063421