K041701

JUL 22 2004

510(k) Summary

CR25.0

Common/Classification Name: Computed Radiography, 21 CFR 892.1650

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

Contact: Jeffery A. Jedlicka, Prepared: June 17, 2004

A. LEGALLY MARKETED PREDICATE DEVICES

This is a Special 510(k) for Device Modification. The predicate device is the device that was modified to produce the CR25.0, namely the ADC Compact Plus, which was cleared by FDA on. 28 September 2001 as K013138.

B. DEVICE DESCRIPTION

The ADC Compact Plus, the predicate device, is a computed radiology imaging system. Instead of screens and photographic film for producing the diagnostic image, the ADC Compact Plus system utilizes an "imaging plate," a plate coated with photo-stimulatable storage phosphors that are sensitive to X-rays and capable of retaining a latent image. This imaging plate is inserted into a device that scans it with a laser and releases the latent image in the form of light which is converted into a digital bit stream. The bit stream of image data is stored locally and can also be stored in a PACS network in DICOM format.

The **CR25.0** is very similar to the ADC Compact Plus and the ADC Solo. The electronics are being reorganized and made smaller, which will result in lower power requirements. However, the basic principles of operation are unchanged. Instead of upgrading the currently marketed economy system called the ADC Solo, components of the high-end ADC Compact Plus were reintegrated into a compact lower-cost system, resulting is no loss of resolution or other measures of image quality.

C. INTENDED USE

The CR25.0 is indicated for use to provide diagnostic quality images to aid in physician diagnosis. The CR25.0 is intended to be used mainly in

chest, skeletal, and gastro-intestinal x-ray imaging applications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **CR25.0** has the same indications for use as the legally marketed predicate device, so the first decision point in the 510(k) Decision Algorithm is straight-forward. The **CR25.0** has the same technological characteristics as the predicate device. This premarket notification has described most of the characteristics of the **CR25.0** in sufficient detail to assure substantial equivalence. For the few characteristics that may not be precise enough to ensure equivalence, performance data was collected, and this data demonstrates substantial equivalence. In keeping with the format of a Special 510(k) for Device Modification, performance data were not included in the submission, but the declarations in **Section IV** provide certification that the data demonstrate equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

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

F. TESTING

The CR25.0 has been tested for proper performance to specifications through various in-house reliability and imaging performance demonstration tests. The device also meets the requirements of EN 60601-1-1 and EN 60601-1-2.

G. CONCLUSIONS

This Special 510(k) for Device Modification submission 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

Mr. Jeffery A. Jedlicka
Manager of Regulatory Affairs
AGFA Corporation
Healthcare
10 South Academy Street
GREENVILLE SC 29601

Re: K041701
Trade/Device Name: CR25.0
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 22, 2004
Received: June 22, 2004

AUG 23 2013

Dear Mr. Jedlicka:

This letter corrects our substantially equivalent letter of July 22, 2004.

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: CR25.0

Indications For Use:

The CR25.0 is indicated for use to provide diagnostic quality images to aid in physician diagnosis. The CR25.0 is intended to be used mainly in chest, skeletal, and gastro-intestinal x-ray imaging applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041701