NOV 1 4 2001

K012750

510(k) Summary

ADC Pediatric

Common/Classification Name: Computed Radiography, 21 CFR 892.1630

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

Contact: Jeff Jedlicka, Prepared: June 22, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

The predicate device is the previous version of the same device, namely the ADC Compact, which was cleared by FDA on 09 March 1998 as K974597.

B. DEVICE DESCRIPTION

The ADC Compact, the predicate device, is a computed radiography imaging system. Instead of screens and photographic film for producing the diagnostic image, the ADC Compact 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 the PACS network in DICOM format.

The **ADC Pediatric** is identical in hardware and software to the ADC Compact. The only difference is in a data file that is provided that is accessed by the (unchanged) software, where preselected image processing parameters are paired with typical pediatric exposure parameters by age and exam type (assuming that the exposures follow the *European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics*). Rather than entering the exposure parameters manually, as would be the case for pediatric exams using the ADC Compact, the user would simply select the exam and patient age, and the proper image processing parameters would be selected automatically and applied to the image.

C. INTENDED USE

The ADC Pediatric is indicated for use to provide diagnostic quality images to aid in physician diagnosis. The ADC Pediatric is intended to be used in pediatric imaging applications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **ADC Pediatric** has the same indications for use as the legally marketed predicate device except for the explicit inclusion of pediatric applications. This change does not affect the intended diagnostic effect. The **ADC Pediatric** has the same (identical) technological characteristics as the predicate device. This premarket notification has described the characteristics of the **ADC Pediatric** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

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

F. TESTING

The ADC Pediatric was tested in two hospitals to refine the image processing parameter sets for pediatric applications. Images were exposed according to the recommendations of the ***European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics,*** and the parameter sets were optimized for those exposures.

G. CONCLUSIONS

This pre-market 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

Agfa Corporation
% T. Whit Athey, Ph.D.
Senior Consultant
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12300 Twinbrook Pkwy, Suite 625
ROCKVILLE MD 20850

AUG 23 2013

Re: K012750
Trade/Device Name: ADC Pediatric Computed Radiographic (CR) Medical Imaging Device
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 16, 2001
Received: August 16, 2001

Dear Dr. Athey:

This letter corrects our substantially equivalent letter of November 14, 2001.

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.

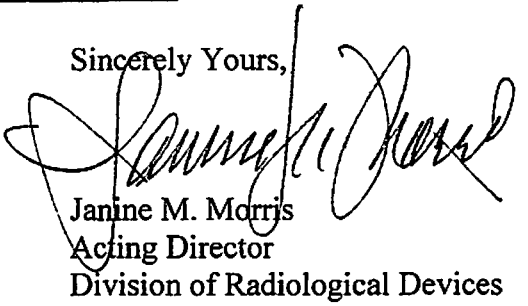
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

NOV 1 4 2001

STATEMENT OF INDICATIONS FOR USE K012750

510(k) Number (if known): K012750

Device Name: ADC Pediatric

Indications For Use:

The ADC Pediatric is indicated for use to provide diagnostic quality images to aid in physician diagnosis. The ADC Pediatric is intended to be used in pediatric imaging applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012750