K974597

MAR 10 1998

1. 510(k) SUMMARY

The ADC COMPACT is a Computed Radiography Imaging System. This system replaces conventional X-Ray cassettes that contain one or two intensifying screens and photographic light sensitive film. Computed radiography utilizes filmless cassettes. Instead of screens and photographic film to obtain the diagnostic image, the system employs what is termed as an *imaging plate*. This plate is coated with photo stimulatable storage phosphors that are sensitive to the X-Ray energy, and capable of retaining a latent image. This imaging plate is inserted into a device that scans it and releases the latent image in the form of light which is converted into a digital bit stream. This bit stream of image data is stored, and introduced to the PACS (Picture Archiving and Computerized System) network in DICOM format.

The major difference between the ADC COMPACT and the previous model in commercial distribution is the actual physical size of the portion of the system that reads and digitizes the imaging plates.

The ADC COMPACT is substantially equivalent to the previous model produced by AGFA, the proprietary name being the ADC 70 (K904519A). It is also substantially equivalent to other computed radiography systems produced by other manufacturers and currently in commercial distribution. AGFA has conducted adequate safety and effectiveness testing in clinical environments that would be relevant to an assessment of substantial equivalence.

System labeling has been conducted in a fashion consistent with the applicable sections of the Code of Federal Regulations (CFR 21).

The software employed by the ADC COMPACT has been evaluated and verified with respect to *level of concern* utilizing the methods suggested by the Office of Device Evaluation (ODE). The method of risk estimation used was the *likelihood* and *severity* model as adapted from the IEC 601-1-4 Standard. The result is that the software risk falls clearly into *the Broadly Acceptable*, or *Lower Level of Concern* range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 1998

Michael Sullivan
Official Correspondent
Bayer Corporation, AGFA Division
100 Challenger Rd.
Ridgefield Park, NJ 07660

Re: K974597
ADC Compact Computed Radiography System
Dated: December 8, 1997
Received: December 9, 1997
Regulatory class: II
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Sullivan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER:

DEVICE NAME:

Indications For Use:

To provide diagnostic quality images for aid in physician diagnosis. This is used in the X-Ray imaging modality, mainly in Chest, Skeleton, and Gastro-Intestinal imaging applications.

11/10/97

Michael Sullivan
Official Correspondent

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974597

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

AGFA