K993665

NOV 1 2 1999

**GE Medical Systems**

*General Electric Company*
*PO Box 414, Milwaukee, WI 53201*

# SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter:

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: September 29, 1999

Identification of Product: Legend CRF Fluoro and Rad System

Classification Name: Stationary X-ray System

Manufacturer:
Medicor X-ray Co.
H-1097, Budapest
Illatos ut 9, Hungary

Device Description: The Legend CRF Fluoro and Rad System consists of an X-ray generator, angulating table with X-ray tube and collimator, image intensifier and spot film device. Optionally, the following items may also be part of the system:
-The table may be provided with an undertable bucky for use with an X-ray tube mounted on a ceiling mounted X-ray tube hanger.
-A basic radiographic table for use with an X-ray tube mounted on a ceiling mounted X-ray tube hanger may be included with the system.
-A separate, vertical bucky stand may also be provided for chest or other general purpose radiographic procedures.

Indications for Use: The Legend CRF Fluoro and Rad System is designed to perform general purpose radiographic and fluoroscopic x-ray examinations. This device is not intended for mammographic applications.

Conformance: The Legend CRF Fluoro and Rad System will conform to applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL 2601-1, IEC 60601-1, and IEC 601-1-2.

Conclusions: GE considers the Legend CRF Fluoro and Rad System to be equivalent to other marketed devices with the same indications for use and meeting similar standards.

## Manufacturer's Statement of Substantial Equivalence

**Statement of Indications for Use:**
The Legend CRF Fluoro and Rad System is indicated for use in generating radiographic and fluoroscopic images of human anatomy in all general purpose X-ray diagnostic procedures. This device is not intended for mammographic applications.

The Legend CRF Fluoro and Rad System consists of an X-ray generator, angulating table with X-ray tube and collimator, image intensifier and spot film device. Optionally, the following items may also be part of the system:

- The table may be provided with an undertable bucky for use with an X-ray tube mounted on a ceiling mounted X-ray tube hanger.
- A basic radiographic table for use with an X-ray tube mounted on a ceiling mounted X-ray tube hanger may be included with the system.
- A separate, vertical bucky stand may also be provided for chest or other general purpose radiographic procedures.

**Claims:**
The Legend CRF Fluoro and Rad System provides excellent image quality, patient positioning, x-ray generation, operator control, system maintenance and dose management. These features make the system easy to use and reliable, providing high quality R&F images.

This notification contains all of the information required by 21CFR 807.87. A completed copy of the "DRAERD Premarket Notification 510(k) Reviewers Screening Checklist" is attached.

The subject device conforms to the following mandatory and voluntary standards:

- 21CFR Subchapter J
- UL 2601-1
- IEC 60601-1
- IEC 60601-2

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. The subject device is not a kit.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21CFR 807.87(j)).

Manufacturer: General Electric Medical Systems

Official Correspondent:

D Mueller FOR:

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager

9/29/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2 1999

General Electric Medical Systems
c/o Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, CT 06470

Re: K993665
Trade Name: Legend CRF Fluoro and Rad System
Regulatory Class: II
Product Code: 90-KPR and 90-JAA
Dated: October 21, 1999
Received: October 29, 1999

Dear Mr. Krumme:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K993665

Device Name: Legend CRF Fluoro and Rad System

## Indications for Use

The Legend CRF Fluoro and Rad System is indicated for use in generating radiographic and fluoroscopic images of human anatomy in all general purpose X-ray diagnostic procedures. This device is not intended for mammographic applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993665