



K982196

GE Medical Systems

OCT 6 1998

General Electric Company
P.O. Box 414 Milwaukee WI 53201-0414

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: 19 June, 1998

Identification of Product: Digital Radiographic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices: The SG60 vertical wallstand was pre-Amendment and the SCX radiographic system was introduced in 1986 (K862120). Subsequently, these were used with the Ultraset-SA Collimator (K894142), the Maxiray 100 Radiographic Tube (K812915), and the SCPU Generator (K940277).

Device Description: The Digital Radiographic Imaging System is designed to perform radiographic examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing and storage. The Digital Radiographic Imaging System consists of a wallstand, tubestand, x-ray tube, collimator, system controller, generator and digital detector.

Indications for Use: The Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film / screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with Predicate:

It is the opinion of GE Medical Systems that the Digital Radiographic Imaging System is of comparable type and substantially equivalent to the Advantx Radiographic System (originally cleared as the SCX K862120) combined with a SG-60 vertical wallstand with respect to intended use, radiation characteristics and image quality. The Digital Radiographic Imaging System presents no new safety concerns. It will comply with the x-ray requirements of 21CFR as well as safety requirements of UL2601-1, IEC601-1 and collateral standards.

Summary of Studies:

Two radiologists at each of three hospitals evaluated 30 paired digital and film / screen images of representative anatomical areas, and found that the digital images had equivalent or better image quality.

Conclusions:

GE considers the Digital Radiographic Imaging System to be equivalent with the predicate device. Digital Radiographic Imaging System provides radiograms that result in equivalent or better imaging performance than film / screen images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- A Hazard Analysis
- A Software Development and Validation Process
- External validations of paired sets of film / screen image and digital images by three different research hospitals to assess the diagnostic equivalence of the digital images.



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

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
General Electric Company
PO Box 414
MILWAUKEE WI 53201

AUG 20 2013

Re: K982196
Trade/Device Name: GE Digital Radiographic Imaging System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: September 4, 1998
Received: September 8, 1998

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of October 6, 1998.

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.

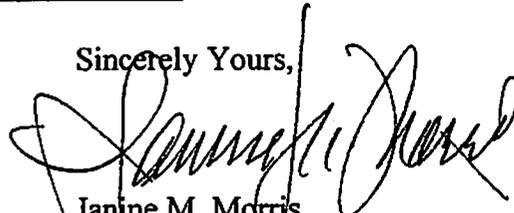
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

A handwritten signature in black ink, appearing to read "Janine M. Morris". The signature is fluid and cursive, with a large initial "J" and "M".

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K982196

Device Name: Digital Radiographic Imaging System

Indications for Use

The Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose 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 ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____

David A. Stinson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982196