

AUG 30 1999



GE Medical Systems

General Electric Company
PO Box 414, Milwaukee, WI 53201

SUMMARY OF SAFETY AND EFFECTIVENESS

K992066

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: June 15, 1999

Identification of Product: Revolution TX/i Digital Radiographic Table System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53118

Marketed Devices: Digital detector (part of Digital Radiographic Imaging System, renamed Revolution XQ/i system) (K982196); SCX (Advantx) radiographic system (K862120); Ultranet-SA Collimator (K894142); Maxiray 100 Radiographic Tube (Pre-amendment); SCPU Generator (K940277) and SG100 vertical bucky stand (Pre-amendment).

Device Description: The Revolution TX/i Digital Radiographic Table System is designed to perform radiographic x-ray 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 Revolution TX/i Digital Radiographic Table System consists of a an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, collimator, system controller, and generator. A separate, conventional SG100 vertical bucky stand is provided for chest or other general purpose radiographic procedures.

Indications for Use: The Revolution TX/i Digital Radiographic Table 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: The Revolution TX/i Digital Radiographic Table System is substantially equivalent to the Revolution XQ/i system, originally cleared as Digital Radiographic Imaging System in 510(k) K982196. The table used in the Digital Radiographic Table System is substantially equivalent to the Compax 40E table cleared in 510(k) K884930.

Summary of Studies: The device has the same detector and acquisition system as the predicate device, and the same intended uses. It will be evaluated for conformance with UL and IEC safety standards. We consider the device to be substantially equivalent to the predicate device.

Conclusions: GE considers the Revolution TX/i Digital Radiographic Table System to be equivalent with the predicate device. The TX/i Digital Radiographic Table System provides radiographic images that result in equivalent or better diagnostic capabilities 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
- Certification to applicable UL and IEC safety standards
- External evaluations



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 20 2013

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

Re: K992066

Trade/Device Name: Revolution TX/I Digital Radiographic Table System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: June 17, 1999
Received: June 18, 1999

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of August 30, 1999.

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.

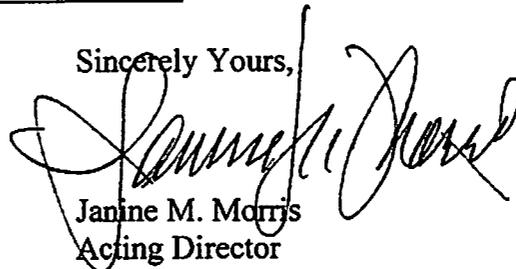
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

STATEMENT OF INTENDED USE

510(k) Number (if known): K992066

Device Name: Revolution TX/i Digital Radiographic Table System

Indications for Use

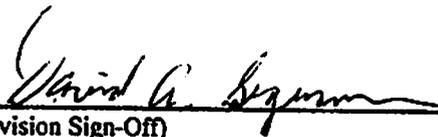
The Revolution TX/i Digital Radiographic Table System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

(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 _____



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992066