K051967

AUG 9 - 2005

Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Submitter: GE Healthcare
3000 N. Grandview Blvd.
Waukesha, WI 53188

Contact Person: John L. Schmidt
Safety and Regulatory Engineering
Telephone: 262-548-4964; Fax: 262-548-2032

Date Prepared: July 15, 2005

Device Name: Revolution XR/d Digital Radiographic Imaging System with Tomosynthesis

Marketed Device: Revolution XR/d Digital Radiographic Imaging System, 510(k) Number K012389, Tomo-Link, K944967, currently in commercial distribution.

Device Description: The Revolution XR/d with Tomosynthesis is designed to perform radiographic x-ray examinations using digital Tomosynthesis acquisition techniques. Tomosynthesis is a hardware & software option to the Revolution XR/d Digital Radiographic X-ray System. The system consists of an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, Overhead Tube Support (OTS), collimator, system controller, generator, and tilting radiographic wall stand with integrated digital detector.

Indications for Use: The Revolution XR/d with Tomosynthesis is intended for use in generating Tomographic images of human anatomy. It is not intended for mammographic use.

Comparison with Predicate Device: Revolution XR/d with Tomosynthesis is an enhanced version of and substantially equivalent to the predicate Tomo-Link (K944967) and Revolution XR/d (K012389).

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety standards, as confirmed by a Nationally Recognized Test Laboratory.

Clinical Tests: Clinical tests under the authority of an IRB show that Tomosynthesis diagnostic capability is as good as the Tomo-link linear tomographic device.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed Tomo-Link and the Revolution XR/d Radiographic Imaging System. The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Healthcare that the modified medical device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Mr. John L. Schmidt
Safety and Regulatory Engineer
GE Healthcare
GE Medical Systems LLC
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K051967
Trade/Device Name: Revolution XR/d with Tomosynthesis
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: II
Product Code: KPR, MQB, and IZF
Dated: July 15, 2005
Received: July 20, 2005

Dear Mr. Schmidt:

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 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 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K051967

Device Name: Revolution XR/d with Tomosynthesis

Indications for Use

Revolution XR/d Digital Radiographic Imaging System is indicated for use in generating Tomographic images of human anatomy. 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 G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051967