APR 8 2005

Attachment B:

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

K050704

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

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: John L. Schmidt
Safety and Regulatory Engineering
Telephone: 262-548-4964; Fax: 262-544-3863

Date Prepared: March 15, 2005

Device Name: Revolution XR/d Digital Radiographic Imaging System with Image Pasting and Autopositioning
21 CFR 892.1680 and 892.1650; 90 KPR and 90 MQB

Marketed Device: Revolution XR/d Digital Radiographic Imaging System, 510(k) Number K012389, Image Pasting Application, K042602, currently in commercial distribution.

Device Description: The Revolution XR/d with Image Pasting and Autopositioning is the latest version of the Revolution XR/d digital radiographic x-ray system. It includes features and functions that have been developed since the introduction of the original XR/d in 2001. Auto image pasting enables the operator to electronically join several sequentially acquired radiographs into a single image (such as spine images). Autopositioning offers improved end user workflow by minimizing the number of steps needed to set up and initiate imaging.

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

Comparison with Predicate Device: Revolution XR/d with image pasting and autopositioning is substantially equivalent to the predicate Revolution XR/d, with image pasting application option. The features and functions available on the new version XR/d offer improved workflow and ease-of-use to the operator, but do not alter the intended use of the device.

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: None required.

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 Revolution XR/d Radiographic Imaging System with Image Pasting Application. 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 Medical Systems that the modified medical device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market including Revolution XR/d.

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

Mr. John L. Schmidt
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General Electric Co.
GE Medical Systems LLC
PO Box 414
MILWAUKEE WI 53201

AUG - 9 2013

Re: K050704
Trade/Device Name: Revolution XR/D Digital Radiographic Imaging System
With Image Pasting Autopositioning
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: March 16, 2005
Received: March 18, 2005

Dear Mr. Schmidt:

This letter corrects our substantially equivalent letter of April 8, 2005.

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 INDICATIONS FOR USE

510(k) Number (if known): K050704

Device Name: Revolution XR/d Digital Radiographic Imaging System with Image Pasting and Autopositioning

Indications for Use

Revolution XR/d Digital Radiographic Imaging System with Image Pasting and Autopositioning is indicated for use in generating radiographic 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 ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050704