K042602

JAN 13 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 Medical Systems
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Milwaukee, WI 53201

Contact Person: Mark M Stauffer
Safety and Regulatory Engineering
Telephone: 262-544-3217; Fax: 262-544-3863

Date Prepared: September 14, 2004

Device Name: Image Pasting application for Revolution XR/d Digital Radiographic Imaging System
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, currently in commercial distribution.

Device Description: Image pasting allows the operator to generate 2 to 5 sequential radiographic images and electronically join them to create a single electronic image.

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 and Revolution XR/d with image pasting application are used to generate radiographic images of human anatomy. Each device is capable of capturing image data digitally or, at the user's preference, on film. Each device has one solid state x-ray detector in the patient table and another in the motorized wallstand. The detectors have a 41 cm by 41 cm surface for capturing x-radiation. On occasion a radiologist desires a radiograph covering an area larger than that of the detector. Using Revolution XR/d (or any analog radiographic system) the technician will use an oversized film cassette, on which either one wide-angle or several smaller overlapping exposures will be made. Using Revolution XR/d with image pasting the technician will be able to make several digital exposures and electronically join them together for viewing as a single, longer radiograph.

The composition of the two systems is nearly identical. Modifications are made to Revolution XR/d to enable the image pasting application. This is described in more detail in item 2.3.2 on page 5.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with 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. The design and development process of the manufacturer conforms with 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. Mark M. Stauffer
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Diagnostic X-ray Engineering
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AUG 23 2013

Re: K042602
Trade/Device Name: Revolution XR/d Digital Radiographic X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. Stauffer:

This letter corrects our substantially equivalent letter of January 13, 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): K042602

Device Name: Image Pasting Application for Revolution XR/d Digital Radiographic Imaging System

Indications for Use

Image Pasting Application for Revolution XR/d Digital Radiographic Imaging System 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)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042602