K132261
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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 18, 2013
Submitter:	GE Healthcare, (GE Medical Systems, LLC) 3000 N. Grandview Blvd. W-709 [Waukesha, WI. 53188]
Primary Contact Person:	John L. Schmidt Regulatory Affairs Leader - X-Ray GE Healthcare, (GE Medical Systems, LLC) Office: 262-548-4964 eFax: 262-997-1080 Email: John.L.Schmidt@ge.com
Secondary Contact Person:	Steven J. Kachelmeyer Regulatory Affairs Director -X-Ray GE Healthcare, (GE Medical Systems, LLC) 262-548-2432 Email: Steven.Kachelmeyer@ge.com
Device Trade Name:	Discovery XR656 with VolumeRAD
Common/Usual Name:	Digital Radiographic X-Ray System
Classification Names: Product Code:	Stationary X-Ray System (21CFR § 892.1680), solid state x-ray imager (21CFR § 892.1650) and Tomographic x-ray system (892.1740 KPR, MQB and IZF
Predicate Device(s):	Stationary X-Ray System, MODEL: Discovery XR656 with VolumeRAD (K051967) (aka Revolution XR/d with Tomosynthesis)
Marketed Devices:	Previous name changes included Definium 8000 and Optima XR640/Discovery 650 where the XR640 is a de-featured version of the system without advanced features like VolumeRAD. VolumeRAD is the GE name for the Digital Tomosynthesis feature.
Device Description:	The Discovery™ XR656 with VolumeRAD extended claims remains a radiographic X-ray system capable of generating

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	radiographic and tomographic images of human anatomy. The Discovery XR656 is designed to handle radiographic applications using GE's flat-panel wireless digital detector. The digital detector is comprised of amorphous silicon and cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing and storage. The Discovery XR656 Digital Radiographic Imaging system consists of a Wallstand, elevating table, overhead Tube support, X-ray tube, collimator, system controller, X-ray generator, and wireless/tethered digital detector. Various configurations are available to meet radiographic requirements. The Optima XR640 version of this product does not include advanced applications and uses the tethered version of the digital detector. The Discovery XR656 offers a wide range of advanced clinical applications including GE's VolumeRAD™ (Digital Tomosynthesis), Dual Energy Subtraction, Tissue Equalization and Auto Image Paste. This 510(k) is to expand our marketing claims for lung nodule detection using the VolumeRAD application. There is no change in design, manufacturing, materials or energy source of the already cleared device. All the abilities required to achieve the results of the extended claims during the clinical trial were available at the initial release of the system.
Intended Use:	General Purpose Digital Radiographic Imaging System
Indication for Use:	The Discovery XR656 is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams. When the VolumeRAD option is included on the system, the system can generate tomographic images of human anatomy including the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. When the VolumeRAD option is used for patients undergoing thoracic imaging, it is indicated for the detection of lung nodules. VolumeRAD generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodules versus posterior-anterior and left lateral views of

	the chest, at a comparable radiation level. The device is not intended for mammographic applications.

Determination of Substantial Equivalence:	Summary of Clinical Tests: A Multi-centered clinical study was performed to demonstrate that the use of VolumeRAD increases physician accuracy in the detection of lung nodules 3-20mm in diameter, when compared to conventional two-view CxR (posterior-anterior (PA) and left lateral (LAT)), at an average effective dose less than 0.1mSv. Summary of Non-Clinical Tests: The Discovery XR656 with extended claims employs the same design, manufacturing, materials or energy source of the already cleared device and complies with voluntary standards. It is certified to comply with the X-ray requirements of 21 CFR, as well as safety requirements of IEC 60601-1 and associated collateral and particular standards. In addition, verification and validation testing is done as required by GE Healthcare' quality system.
Conclusion:	The Discovery XR656 with its Extended Claims for VolumeRAD does not result in any new potential safety risks and performs as well as the currently marketed Discovery XR656. With the extended VolumeRAD claims, the Discovery XR656 with VolumeRAD has demonstrated effectiveness beyond the original limited claims of the VolumeRAD feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 18, 2013

GE Medical Systems, LLC
% Mr. John Schmidt
Regulatory Affairs Leader – X-Ray
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K132261
Trade/Device Name: Discovery XR656 with VolumeRAD (digital tomosynthesis)
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: II
Product Code: IZF, KPR and MQB
Dated: August 28, 2013
Received: August 30, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

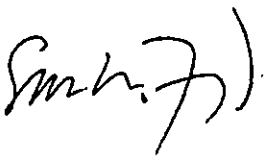
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

GE Healthcare
510(k) Premarket Notification Submission

Indications for Use

510(k) Number (if known): K132261

Device Name: Discovery XR656 with VolumeRAD

Indications for Use:

The Discovery XR656 is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams.

When the VolumeRAD option is included on the system, the system can generate tomographic images of human anatomy including the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages.

When the VolumeRAD option is used for patients undergoing thoracic imaging, it is indicated for the detection of lung nodules. VolumeRad generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodules versus posterior-anterior and left lateral views of the chest, at a comparable radiation level.

The device is not intended for mammographic applications.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)