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510(K) Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92.

Date Prepared: September 3, 2010

Submitter: GE Healthcare, (GE Medical Systems, LLC)
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DEVICE INDENTIFICATION

Trade Name: GE Wireless DR Imaging Option – WDR1

Common/Usual Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)

Classification Name: Solid State X-ray Imager (flat panel/digital imager)
Class II, MQB, 21CFR 892.1650

DEVICE DESCRIPTION:

The Wireless DR Imaging Option - WDR1 consists of a wireless detector, system interface box, computer, display, keyboard and mouse. It is designed to acquire digital radiographic images when used with existing radiographic x-ray systems. Images captured can be communicated to the system via wireless signal, tethered cable or direct connection (docked). The Wireless detector is very similar to the digital detector currently in use as the GE Digital Radiographic Detector (K982196), and the Philips

Medical Systems Wireless Portable Detector FD-W17 (K090625) comprised of amorphous silicon with a cesium iodide scintillator.

It is used on radiographic X-ray systems as a substitute for film/screen systems or CR systems. The Radiographic X-ray system remains unchanged except for the replacement of the systems receptor with the Wireless WDR1 detector.

INDICATIONS FOR USE:

The Wireless DR Imaging Option -WDR1, when used with a radiographic imaging system, is indicated for use in generating radiographic images of human anatomy. It is intended for use in all routine radiography exams, and specialized areas including pediatric work, intensive care and trauma, wherever conventional screen-film systems or CR systems maybe used.

The device is not intended for mammography or fluoroscopy applications.

COMPARISON WITH PREDICATE DEVICES:

The Wireless DR Imaging Option - WDR1 is an enhanced wireless version of and substantially equivalent to, the GE Digital Radiographic Detector cleared under 510(k) number K982196 and Philips Medical Systems wireless detector FD-W17 (K090625). It involves changes from the predicate device (K982196) to add wireless functionality, reduced weight and power, and modifications in design that involve hardware, software, and firmware. The Wireless DR Imaging Option WDR1 and the predicate devices are both for use in acquiring digital radiographic images and have similar indications for use.

Changes in electronics, hardware and firmware have been made to affect these power and weight reductions, but there is no fundamental change in X-ray detection technology, or image creation, and uses virtually identical operating principles to the GE Digital Radiographic Detector currently marketed system (K982196). It has the same technological characteristics related to safety and effectiveness as the predicate devices. A review of all bench and standards testing indicate that the new device provides no new safety concerns and is as safe an effective as the predicate devices.

The Wireless DR Imaging Option - WDR1 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.

ADVERSE EFFECTS ON HEALTH:

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.

The potential hazards of electrical and mechanical are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards.
- Compliance to applicable CDRH 21 CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

CONCLUSION:

The Wireless DR Imaging Option - WDR1 is an evolutionary modification to the GE Digital Radiographic Detector. It does not result in any new potential safety risks, has the same technological characteristics, and performs as well as the devices currently on the market. The Wireless DR Imaging Option WDR1 will be 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.

After analyzing standards testing and bench data, it is the conclusion of GE Healthcare that the Wireless DR Imaging Option - WDR1 is substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.

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 J. Schmidt
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GE Medical Systems, LLC
3000 N. Grandview Blvd.
WAUKESHO WI 53188

AUG 23 2013

Re: K102615
Trade/Device Name: Wireless DR Imaging Option-WDR1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 2, 2010
Received: September 9, 2010

Dear Mr. Schmidt:

This letter corrects our substantially equivalent letter of November 18, 2010.

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

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Indications for Use

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510(k) Number (if Known): K102615

Device Name: Wireless DR Imaging Option – WDR1

Indications for Use:

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Prescription Use_X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Part 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 Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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