K141381
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JUN 12 2014

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	March 21, 2014	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, ZhongYuan Road, Suzhou Industrial Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Establishment Registration Number: Not registered yet	
Contact Person:	Gordon Shu Regulatory Affairs Manager Phone: +86-512-67336804 Fax: +86-512-68018677 E-mail: Gordon.Shu@philips.com	
Trade Name:	DuraDiagnost	
Common Name:	Digital Diagnostic Radiographic System	
Classification:	Classification Name:	Stationary X-Ray System
	Classification Regulation:	21CFR §892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Classification Product Code:	KPR (System, X-Ray, Stationary)
	Subsequent Product Code:	MQB (solid state x-ray imager (flat panel/digital imager)
Predicate Device 1:	Trade Name:	Brivo XR385, Digital Diagnostic Radiographic System
	Manufacturer:	GE MEDICAL SYSTEM, LCC
	510(k) Clearance:	K103448 (August 12, 2011)
	Classification Regulation:	21 CFR, Part 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	KPR

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Predicate Device 2:	Trade Name:	Philips BuckyVision
	Manufacturer:	Philips Medical Systems, Inc.
	510(k) Clearance:	K982795 (November 24,1998)
	Classification Regulation:	21CFR §892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	KPR & MQB
Predicate Device 3:	Trade Name:	ddRVersa™ Motion
	Manufacturer:	Swissray Medical AG
	510(k) Clearance:	K123005 (December 7, 2012)
	Classification Regulation:	21CFR §892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Device Code:	KPR & MQB

Device description:

The Philips DuraDiagnost Digital Diagnostic Radiographic System (DuraDiagnost) is a flexible digital radiography (DR) system that is designed to provide fast and smooth radiography examinations of sitting, standing or lying patients. The Philips DuraDiagnost consist of the following components: Tube column with X-ray assembly, wall stand with detector carrier, patient table with detector carrier and floating table top, high voltage generator, and acquisition and reviewing workstation for post-processing, storage and viewing of images. Images may be transferred via a DICOM network for printing, storage and detailed review.

Indications for Use:

The DuraDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Summary of the Technological Characteristics & Fundamental Scientific Technology:

The components of the Philips DuraDiagnost employ similar basic construction and fundamental scientific technology as provided with the currently marketed and predicate GE Brivo XR385 and Philips BuckyVision with regards to the functionality of the following components: Integrated tube column, patient table with a floating table top, high-voltage generator, dual-focus rotation anode X-Ray tube, manual beam limiting device, digital detector, wall stand and workstation for images post-processing, storage and viewing (See the comparison Table provided below, comparing the Philips DuraDiagnost to the currently marketed predicate devices). The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the Philips DuraDiagnost when compared to the currently marketed and predicate devices.

The wireless portable detector (Model No. 3543EZ) of the Philips DuraDiagnost is identical to the wireless portable detector (Model No. 3543EZ) of the currently marketed and predicate ddRVersa™ Motion (K123005 – December 7, 2012) – Swissray Medical AG and is manufactured by Trixell. Therefore, both the wireless portable detector of the Philips DuraDiagnost and the wireless portable detector of the currently marketed and predicate ddRVersa™ Motion employ identical fundamental scientific technology.

Based on the information provided above, the Philips DuraDiagnost is considered substantially equivalent to the currently marketed and predicate device, GE Brivo XR385 (K103448 – August 12, 2011) and Philips BuckyVision (K982795 – November 24, 1998) in terms of fundamental scientific technology. With regards to wireless portable detector, the Philips DuraDiagnost is considered substantially equivalent to the currently marketed and predicate ddRVersa™ Motion (K123005 – December 7, 2012) – Swissray Medical AG in terms of fundamental scientific technology.

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Summary of Technological Characteristics of the Philips DuraDiagnost to the Currently Marketed Predicate Devices					
Feature	**Currently marketed and Predicate GE Brivo XR385 (K103448)**	**Currently marketed and Predicate Philips BuckyVision (K982795)**	**Currently marketed and Predicate Swissray ddRVersa™ Motion (K123005)**	**Philips DuraDiagnost**	**Comparison Results**
Design characteristic					
X-ray Tube	Toshiba E7843X	RO 1750 & SRO 33100	Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips **DuraDiagnost**, since it is manufactured by the same manufacturer Trixell.	RO 1750 & SRO 33100	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision both use the identical X-ray tube. Thus, demonstrating SE.
Max Tube Voltage	150kV	150kV		150kV	Identical. Thus, demonstrating SE.
Focal spot size	0.6mm/1.2mm	0.6mm/1.2mm		0.6mm/1.2mm	Identical. Thus, demonstrating SE.
Tube Max power	50KW	50KW/100KW		50KW/100KW	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision both use the identical X-ray tube. Thus, demonstrating SE.
Anode Type	Rotation	Rotation		Rotation	Identical. Thus, demonstrating SE.

Generator	Unknown	EMD Technologies , M-CABINET CXA 50kW, M-CABINET CXA 65kW, M-CABINET CXA 80kW		EMD Technologies , M-CABINET CXA 50kW, M-CABINET CXA 65kW, M-CABINET CXA 80kW	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision both use the identical Generator. Thus, demonstrating SE.
Max Power	50KW	50KW/65KW/80KW		50KW/65KW/80KW	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision both use the identical power. Thus, demonstrating SE.
KV range	40-150	40-150		40-150	Identical. Thus, demonstrating SE.
Milli ampere sec (mAs) product	0.02 mAs-512 mAs(with AEC control)	0.5 mAs-600 mAs (with AEC control)		0.5 mAs-600 mAs (with AEC control)	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision both use the identical mAs. Thus, demonstrating SE.
Collimator					
Operation Mode	Manual collimation	Motorized automatic collimation or manual collimation	Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to	Manual collimation	Same. The Philips **DuraDiagnost** and the currently marketed and predicate GE's Brivo XR385 both use the manual collimation mode. Thus, demonstrating SE.

Shape of Beam	Rectangular	Rectangular	the wireless portable detector (model 3543EZ) of the Philips **DuraDiagnost**, since it is manufactured by the same manufacturer Trixell.	Rectangular	Identical. Thus, demonstrating SE.
Detector					
Type	Digital Detector (Fixed)	Digital Detector (Fixed)	Digital Detector (Wireless)	Digital Detector (Fixed & Wireless)	Identical. The Fixed and Wireless Portable Detector of the Philips **DuraDiagnost** is identical to the currently marketed and predicate GE's Brivo XR385, Philips Bucky Vision and Swissray's ddRVersa™ Motion in terms of the type of the detector. Thus, demonstrating SE.
X-ray Scintillator Material	Gadolinium Oxysulphide (GdOS)	Cesium Iodide	Cesium Iodide	GdOS(Fixed) Cesium Iodide(Wireless)	Identical. The Fixed and Wireless Portable Detector of the Philips **DuraDiagnost** and the currently marketed and predicate GE's Brivo XR385 and Swissray's ddRVersa™ Motion utilize identical scintillator material fabricated from GdOS and Cesium Iodide, respectively. Thus demonstrating SE.
Image Area	40.4cm x 40.4 cm	42.5 cm x 42 cm	42.4cm x 34.8cm (wireless)	43cm x 43cm(Fixed) 42.4cm x 34.8cm (wireless)	Identical for Wireless Portable Detector. The Wireless Portable Detector of the Philips **DuraDiagnost** and

					the currently marketed and predicate Swissray's ddRVersa™ Motion utilize identical image area. Thus demonstrating SE. Similar for Fixed Detector. The slight differences between the image area of the Philips **DuraDiagnost** and the currently marketed and predicate predicate Philips BuckyVision and GE's Brivo XR385 are not anticipated to significantly alter the diagnostic image quality. Thus, demonstrating SE.
Image Matrix Size	2048 x 2048	2874 x 2840	2866 x 2350 (wireless)	2874 x 2869 (Fixed) 2866 x 2350 (wireless)	Identical for Wireless Portable Detector. The Wireless Portable Detector of the Philips **DuraDiagnost** and the currently marketed and predicate Swissray's ddRVersa™ Motion utilize identical image matrix size. Thus demonstrating SE. Similar for Fixed Detector. The slight differences between the image matrix size of the Philips **DuraDiagnost** and the currently marketed and predicate

					predicate Philips BuckyVision and GE's Brivo XR385 are not anticipated to significantly alter the diagnostic image resolution. Thus, demonstrating SE.
Analog / Digital (A/D) conversion	14 bits	16 bits	16 bits	16 bits	Identical. The Philips **DuraDiagnost** and the currently marketed and predicate Philips BuckyVision and Swissray's ddRVersa™ Motion all use the same A/D conversion. Thus, demonstrating SE.
Source to Image Distance (SID)					
Source to Image Distance (SID)	Table: 50-110cm; Wallstand: 100-180cm	SID depends on different configurations, because BuckyVision is ceiling suspension X-ray system.	Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips **DuraDiagnost**, since it is manufactured by the same manufacturer Trixell.	Table: 40-115cm; Wallstand: 110-245cm	The slight differences between the SID of the proposed DuraDiagnost and the currently marketed and predicate GE's Brivo XR385 are not anticipated to significantly alter the application usage. Thus, demonstrating SE.

External connectivity					
DICOM	DICOM 3.0 compatible	DICOM 3.0 compatible	Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips **DuraDiagnost**, since it is manufactured by the same manufacturer Trixell.	DICOM 3.0 compatible	Same. Thus, demonstrating SE
Software platform					
	Unknown	Eleva workspot (K063781- January 05, 2007)	Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips **DuraDiagnost**, since it is manufactured by the same manufacturer Trixell.	Eleva workspot	Same. The Philips **DuraDiagnost** and the currently marketed predicate Philips BuckyVision both use the same software platform. Thus, demonstrating SE.

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Summary of Non-clinical Performance Data:

Non-clinical performance testing performed on the Philips DuraDiagnost demonstrates compliance with the following International and FDA-recognized consensus standards and FDA Guidance documents:

- AAMI / ANSI ES60601-1: 2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 (consolidated text) Medical electrical equipment –Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-1-3 Edition 2.0 2008-01, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-28 Edition 2.0 2010-03, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
- IEC 60601-2-54 Edition 1.0 2009-06, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.
- IEC 62304 First edition 2006-05, Medical device software - software life cycle processes.
- ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices.
- IEC 62366 Edition 1.0 2007-10, Medical devices - Application of usability engineering to medical devices.
- CFR 1020.30 Diagnostic x-ray systems and their major components.
- CFR 1020.31 Radiographic equipment.

- Device specific guidance document, entitled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices – August 6, 1999."

- FDA's Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – May 11, 2005."
- FDA guidance document entitled, "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff – August 13, 2013."

- FDA draft guidance document entitled, "Pediatric Information for X-ray Imaging Device Premarket Notifications issued on May 10, 2012."

Additionally, verification / validation tests have been performed to address intended use, the technical claims, requirement specifications and the risk management results. The test results demonstrate that Philips DuraDiagnost:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents.
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the Philips DuraDiagnost is substantially equivalent to the currently marketed and predicate device, GE Brivo XR385 (K103448, Aug. 12, 2011) Philips BuckyVision (K982795-Nov.24, 1998) and ddRVersa™ Motion (K123005 - December 7, 2005) - Swissray Medical AG in terms of safety and effectiveness.

Clinical Performance Data:

Clinical study was not warranted to support this 510(k) submission, since substantial equivalence to the currently marketed and predicate devices was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology; and
- Safety and effectiveness.

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Substantial Equivalence Conclusion:

The Philips DuraDiagnost is substantially equivalent to the currently marketed and predicate device GE Brivo XR385 (K103448, August 12, 2011) and Philips BuckyVision (K982795, November 24,1998) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. With regards to the wireless portable detector, the Philips DuraDiagnost is considered substantially equivalent in terms of design and fundamental scientific technology to the currently marketed and predicate ddRVersa™ Motion (K123005 - December 7, 2005) - Swissray Medical AG.

Additionally, substantially equivalence was demonstrated with the following:

- Non-clinical performance (verification / validation) tests, which complied with the requirements specified in the international and FDA recognized consensus standards;

- Tests identified in the FDA device specific guidance document entitled, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices – August 6, 1999." The results of these tests demonstrate that the Philips DuraDiagnost met the acceptance criteria, provides similar diagnostic image quality when compared with the predicate devices and is adequate for its intended use.

- Tests identified in the FDA guidance document entitled, "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff – August 13, 2013." The results of these tests demonstrate that the Philips DuraDiagnost met the acceptance criteria with regards to wireless technology used in the wireless portable Detector and is adequate for its intended use.

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

June 12, 2014

Philips Healthcare (Suzhou) Co., Ltd.
% Mr. Gordon Shu
Regulatory Affairs Manager
No. 258, Zhong Yuan Road
Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K141381
Trade/Device Name: Duradiagnost
Regulation Number: 21 CFR 892.1680
Regulation Name: DuraDiagnost radiographic system
Regulatory Class: II
Product Code: KPR, MQB
Dated: May 20, 2014
Received: May 28, 2014

Dear Mr. Shu:

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.

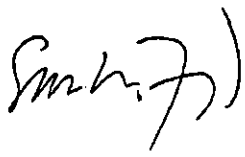
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141381

Device Name
DuraDiagnost

Indications for Use *(Describe)*

The DuraDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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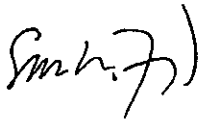
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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