DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 4, 2017

Philips Healthcare (Suzhou) Co., LTD
% Alina Zhou
Q&R Director
No. 258, Zhong Yuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K163410
Trade/Device Name: DigitalDiagnost C50
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 01, 2016
Received: December 05, 2016

Dear Alina Zhou:

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

5 Statement of Indication for Use/Intended Use

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)*

K163410

Device Name
DigitalDiagnost C50

Indications for Use *(Describe)*

The DigitalDiagnost C50 system 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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6 510(k) Summary of Safety and Effectiveness

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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:	November 25, 2016	
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: 3009529630	
Contact Person:	Alina Zhou Q&R Director Phone: +86-512-67336582 Fax: +86-512-68018677 E-mail: Alina.Zhou@philips.com	
Trade Name:	DigitalDiagnost C50	
Common Name:	Digital Radiography 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)
Predicate Device :	Trade Name:	DuraDiagnost
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K141381 (June 12, 2014)
	Classification Regulation:	21 CFR, Part 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	KPR, MQB

Reference Device :	Trade Name:	Nexus DRTM Digital X-ray Imaging System (with PaxScan 4336Wv4)
	Manufacturer:	Varian Medical Systems
	510(k) Clearance:	K161459 (September 06, 2016)
	Classification Regulation:	21CFR §892.1680
	Classification Name:	Solid State X-Ray Imager (flat panel/digital imager)
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	MQB

Device Description

The **Philips DigitalDiagnost C50 Digital Radiography System (Philips DigitalDiagnost C50**) 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 DigitalDiagnost C50** consists of the following components: ceiling suspension with X-ray assembly, wall stand with detector carrier, patient table with detector carrier and floating table top, high voltage generator, and an 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 **Philips DigitalDiagnost C50** is intended for use in generating radiographic images of human anatomy by a 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 DigitalDiagnost C50** employ similar basic construction and fundamental scientific technology as provided with the currently marketed and predicate Philips DuraDiagnost (K141381 – 06/12/2014) with regards to the functionality of the following components: integrated tube assembly, 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 comparing the **Philips DigitalDiagnost C50** to the currently marketed predicate Philips DuraDiagnost provided below.

The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the **Philips DigitalDiagnost C50** when compared to the currently marketed and predicate Philips DuraDiagnost.

The wireless portable detector of the **Philips DigitalDiagnost C50** is identical to the wireless portable detector (PaxScan 4336Wv4) of the currently marketed and reference device, Varian Nexus DR™ Digital X-ray Imaging System (K161459, 09/06/ 2016) manufactured by Varian Medical System. Therefore, both the wireless portable detector of the **Philips DigitalDiagnost C50** and the wireless portable detector of the reference device, Varian Nexus DR™ Digital X-ray Imaging System employ identical fundamental scientific technology.

The Fixed detector (Model No. 4343RG) of the **Philips DigitalDiagnost C50** is identical to the fixed detector (Model No. 4343RG) of the currently marketed and predicate Philips DuraDiagnost and is manufactured by Trixell Company. Therefore, the fixed detector of the **Philips DigitalDiagnost C50** and the currently marketed and predicate DuraDiagnost employ identical fundamental scientific technology.

Summary of Technological Characteristics of the Philips DigitalDiagnost C50 to the Currently Marketed Predicate Devices			
Feature	**Currently Marketed and Predicate Philips DuraDiagnost (K141381, 06/12/2014)**	**Proposed Philips DigitalDiagnost C50**	**Comment**
X-ray Tube	RO 1750 ROT 360 & SRO 33100 ROT 360	RO 1750 ROT 380 & SRO 33100 ROT 380	Both devices utilize similar x-ray tubes. The specifications of both tubes are exactly the same, including nominal X-ray tube voltage, nominal focal spot values, maximum tube current, maximum anode heat content, total filtration (minimum), maximum and anode heat dissipation. The only minor difference is the tube housing which does not affect the performance of the tube and therefore, there is no impact on the safety and effectiveness of the device. Thus, demonstrating SE.
Max Tube Voltage	150kV	Same	No difference; thus, demonstrating SE.
Focal Spot Sizw	0.6mm/1.2mm	Same	No difference; thus, demonstrating SE.
Rube Maz Power	50KW/100KW (250W equivalent anode input power)	Same	No difference; thus, demonstrating SE.
Anode Type	Rotation	Same	No difference; thus, demonstrating SE.
Generator	Philips Healthcare (Suzhou), M-CABINET CXA Pro 50kW, M-CABINET CXA Pro 65kW, M-CABINET Pro CXA 80kW	Philips Healthcare (Suzhou), M-CABINET CXA Pro 50kW, M-CABINET CXA Pro 65kW	Equivalent. The Philips **DigitalDiagnost C50** is provided with 50KW/65KW that is also provided with the currently marketed and predicate Philips DuraDiagnost. Therefore, no impact on the safety and effectiveness of the device. Thus, demonstrating SE.
Max Power	50KW/65KW/80KW	50KW/65KW	
KV range	40-150	Same	No difference; thus, demonstrating SE.
Milli ampere sec (mAs) product	0.4 mAs-600 mAs (with AEC control)	Same	No difference; thus, demonstrating SE.
Collimator			
Operation Mode	Manual collimation	Same	No difference; thus, demonstrating SE.

Shape of Beam	Rectangular	Same	No difference; thus, demonstrating SE.
Detector			
Type	Digital Detector Fixed: GdOS Wireless: Pixium 3543EZ (CSI)	Digital Detector Fixed: GdOS Wireless: PaxScan 4336Wv4 (Gdos)	The Fixed Portable Detector of the Philips **DigitalDiagnost C50** is identical to the currently marketed and predicate Philips DuraDiagnost. The wireless detector is of the Philips **DigitalDiagnost C50** is identical to the Reference Device, Nexus DR™ Digital X-ray Imaging System (K161259, 09/062016 – Varian Medical System.) Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
X-ray Scintillator Material	GdOS (Fixed) Cesium Iodide (Wireless)	GdOS (Fixed) GdOS (Wireless)	The Fixed Portable Detector of the Philips **DigitalDiagnost C50** is identical to the currently marketed and predicate Philips DuraDiagnost. The wireless detector of the Philips **DigitalDiagnost C50** is identical to the Reference Device, Nexus DR™ Digital X-ray Imaging System (K161259, 09/062016 – Varian Medical System.) Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
Image Area	42.5cm x 42.5cm (Fixed) 42.4cm x 34.8cm (wireless)	42.5cm x 42.5cm (Fixed) 42.7 cm x 34.4 cm (wireless)	The image area of the Philips **DigitalDiagnost C50,** provided with the Fixed Portable Detector**,** is identical to the currently marketed and predicate Philips DuraDiagnost. The image area of the Philips **DigitalDiagnost C50,** provided with the wireless detector is identical to the Reference

			Device, Nexus DR™ Digital X-ray Imaging System (K161259, 09/062016 – Varian Medical System.) Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
Image Matrix	2874 x 2869 (Fixed) 2866 x 2350 (wireless)	2874 x 2869 (Fixed) 3072 x 2476 (wireless)	The image matrix of the Philips **DigitalDiagnost C50,** provided with the Fixed Portable Detector**,** is identical to the currently marketed and predicate Philips DuraDiagnost. The image matrix of the Philips **DigitalDiagnost C50,** provided with the wireless detector, is identical to the Reference Device, Nexus DR™ Digital X-ray Imaging System (K161259, 09/062016 – Varian Medical System.) Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
Analog / Digital (A/D) conversion	16 bits	Same	No difference; thus, demonstrating SE.
Source to Image Distance (SID)			
SID	Table: 40-115cm; Wallstand: 110-245cm	SID depends on different configurations, because the **DigitalDiagnost C50** is a ceiling suspension X-ray system.	The slight difference between the SID of the **DigitalDiagnost C50** and the currently marketed and predicate Philips DuraDiagnost does not alter the application usage; as demonstrated through Section 17 bench testing. Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
External Connectivity			
DICOM	DICOM 3.0 compatible	Same	No difference; thus, demonstrating SE.
Software Platform			
Software	Eleva workspot	Same	No difference; thus, demonstrating SE.

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Summary of Non-Clinical Performance Data:

The **DigitalDiagnost C50** complies with the following international and FDA-recognized consensus standards:

- International and FDA-recognized consensus standards:
  - 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 2.1 2013-04, 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 Edition 1.1 2015-06, Medical device software - software life cycle processes.
  - ISO 14971 Second edition 2007-03, Medical devices - Application of risk management to medical devices.
  - IEC 62366 Edition 1.1 2014-01, 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 – September 1, 2016"
- 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 – August 14 2013."
- FDA draft guidance document entitled, "Pediatric Information for X-ray Imaging Device Premarket Notifications issued on May 10, 2012."

Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results.

Non-Clinical verification and or validation test results demonstrate that the **DigitalDiagnost C50**:

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

Therefore, the **DigitalDiagnost C50** is substantially equivalent to the primary currently marketed and predicate Philips DuraDiagnost (K141381- 06/12/2014) in terms of safety and effectiveness.

Summary of Clinical Data:

The **DigitalDiagnost C50** did not require a clinical study since substantial equivalence to the primary currently marketed and predicate device was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

Furthermore, one modification included in this submission is to replace the current wireless detector with an equivalent and already cleared wireless detector by Varian Medical Systems (Varian PaxScan 4336Wv4 of the reference device, Varian Nexus

DR™ Digital X-ray Imaging System (K161459, cleared on 09/06/2016); therefore a clinical image study is not required.

Substantial Equivalence Conclusion:	The **DigitalDiagnost C50** is substantially equivalent to the currently marketed and predicate Philips DuraDiagnost (K141381 - 06/12/2014) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Also, the wireless detector provided with the **DigitalDiagnost C50** is substantially equivalent to the currently marketed and reference device, Varian Nexus DR™ Digital X-ray Imaging System (K161459, 09/06/2016) with regards to the wireless detector (PaxScan 4336Wv4). Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, ES 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, IEC 62304, IEC 62366 and ISO 14971. The results of these tests demonstrate that the **DigitalDiagnost C50** met the acceptance criteria and is adequate for its intended use.