DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 31, 2017

Philips Medical Systems DMC GmbH
% Ming Xiao
Regulatory Affairs Specialist North America
Roentgenstrasse 24-26
Hamburg, 22335
GERMANY

Re: K163210
Trade/Device Name: CombiDiagnost R90
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA, KPR and MQB
Dated: January 17, 2017
Received: January 25, 2017

Dear Ming Xiao:

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

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)*
K163210

Device Name
CombiDiagnost R90

Indications for Use *(Describe)*
CombiDiagnost R90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

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.

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7. 510(k) Summary

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: January 26, 2017

Manufacturer:
Philips Medical Systems DMC GmbH
Roentgenstrasse 24-26
22335 Hamburg
GERMANY
Establishment registration number: 3003768251

Primary Contact Person:
Ming Xiao
Regulatory Affairs Specialist
North America
Phone: +49 40 5078-2306
Fax: +49 40 5078-2425
E-mail: ming.xiao@philips.com

Device Name: ***CombiDiagnost R90***

Classification:

Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR 892.1650
Classification Panel:	90 -- Radiology
Device Class:	Class II
Primary Product Code:	JAA
Secondary Product Codes:	KPR, MQB

Primary Predicate Device:

Trade Name:	Philips EasyDiagnost Eleva
Manufacturer:	Philips Medical Systems DMC
510(k) Clearance:	K031535 – June 17, 2003
Classification Name:	Image-intensified fluoroscopic x-ray system; Stationary x-ray system; Spot-film device; Tilting Radiographic table
Classification Regulation:	21CFR 892.1650; 21CFR 892.1680; 21CFR 892.1670; 21CFR 892.1980
Classification Panel:	Radiology

	Device Class:	Class II
	Product Codes:	JAA, KPR, IXL and IXR
Reference Device:	Trade Name:	Eleva Workspot with SkyFlow
	Manufacturer:	Philips Medical Systems
	510(k) Clearance:	K153318 – Dec 22, 2015
	Classification Name:	Stationary X-Ray System
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product codes:	MQB, LLZ

Device Description:

The *CombiDiagnost R90* is a multi-functional remote controlled fluoroscopy system in combination with a high-end digital radiography system consisting of a floor-mounted tilt- and height-adjustable patient support and a scan unit consisting of a tube and a flat panel detector, Pixium FE 4343F. The tabletop can be moved by a motor in the lateral direction and can be tilted +/- 90 degrees. The scan unit tilts with the table and can be moved in the longitudinal direction, relative to the table and to the patient. The fully integrated system is provided with a touch screen console, glass or metal x-ray tube(s) with collimator and high resolution displays. As a fully integrated system, the proposed CombiDiagnost R90 can be configured with a Philips generator, the flat panel detector Pixium FE 4343F, and the Philips Dynamic Eleva Image Chain acquisition–station also provided with the currently marketed and reference device, Eleva Workspot with SkyFlow (Eleva Workspot). The proposed CombiDiagnost R90 uses the same workflow from the currently marketed and reference device, Eleva Workspot with SkyFlow. The only modification to the Eleva Workspot is integration with the Pixium FE 4343F detector.

Indications for Use:

CombiDiagnost R90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

Fundamental Scientific Technology:

CombiDiagnost R90 is a multi-functional remote controlled fluoroscopy system in combination with high-end digital radiography consisting of a floor-mounted tilt- and height-adjustable patient –

support and a scan unit consisting of a tube and a flat detector. It is designed for fluoroscopy examinations of the recumbent, standing or seated patient and also for lateral exposures. Fine positioning of the tube and collimator on the patient is easy to carry out using control grips and control buttons on table or tube user interfaces. It is quite convenient to be operated in hospitals. *CombiDiagnost R90* is intended for use in generating radiographs of human anatomy by qualified/trained doctors or technicians. 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.

Based on the information provided above, the *CombiDiagnost R90* is considered substantially equivalent to the primary currently marketed and predicate device EasyDiagnost Eleva (K031535, June 17, 2003) in terms of fundamental scientific technology.

Summary of technological characteristics:

This modified device has the same indications for use and technological characteristics as the primary predicate device, EasyDiagnost Eleva. Comparisons of the technological characteristics demonstrate the substantial equivalence to the primary predicate device.

	Primary Predicate Device: EasyDiagnost Eleva (K031535)	***Proposed Device: CombiDiagnost R90 (K163210)***	***Discussion***
Table Features			
Working height (table top center to floorplate)	83cm	62 cm – 142 cm	Similar; the range of working height does not affect the safety or effectiveness of the device.
Table tilt movement	-20° to +90° Optional: -30° to +90° -45° to +90° -85° to +90°	-90° to +90°	Similar: The table tilt movement does not affect the safety or effectiveness of the device.
Table top suspension	Back and sides	Two sides suspensions	Similar: Two side table side suspension does not affect the safety or effectiveness of the device.
Table top material	Plastic laminate or carbon fiber	Same	Equivalent.
Table top movement	Lateral: -10 cm to + 9 cm Longitudinal: ± 83 cm	Same	Equivalent
Table top absorption	0.7mm typical (@ 100kV, 2.7mm Al HVL)	Plastic, with Carbon fiber: 0.6mm Al @ 100kV, HVL = 3.6mm Al	Similar: Minor differences in the table top absorption does not affect the safety or effectiveness of the device.
Maximum patient weight	180 kg	284 kg (626 lbs)	The proposed *CombiDiagnost R90* is able to hold more

	Primary Predicate Device: EasyDiagnost Eleva (K031535)	***Proposed Device: CombiDiagnost R90 (K163210)***	***Discussion***
			patient weight; this does not affect the safety or effective-ness of the device.
Lateral scan distance	22 cm	32 cm ± 16 cm	Similar: The range of lateral scan distances provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device.
Lateral scan speed	Manual Movement	5 cm/s, soft start and stop Auto centering	The automated lateral scan speed provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device.
Longitudinal scan distance	75 cm	160 cm longitudinal, motorized	Similar: The extended longitudinal motorized scan distance of the proposed *CombiDiagnost R90* does not affect the safety or effective-ness of the device.
Longitudinal scan speed	Manual Movement (Servo Support)	3 cm – 20 cm / sec	Similar: The longitudinal scan speed provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device
Table column angulation	N/A	-40° to +40°	The table angulation provided with the proposed *CombiDiagnost R90* does not affect the safety or effective-ness of the device.
Source image distance	73cm – 103cm, 88cm – 118cm with Geomat in extended position	113cm – 183cm	Similar: The source image distance provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device.
Collimator	Square / rectangular plus Iris	Motorized automatic collimation	The motorized collimator provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device.
Preparation time for exposure	0.4 – 1.8 sec (depends on X-ray Tube and technique)	1 sec (approximately)	Similar: The minor difference in the preparation time does not affect the safety or effectiveness of the device.
Grid	Parkable	Same	Equivalent: No effect on the safety or effectiveness of the device.
Auto Grid Selection	Yes	Same	Equivalent: No effect on the safety or effectiveness of the device.
Automatic pre-position of the table	No	Yes	The automatic pre-position of the table provided with the proposed *CombiDiagnost R90* does not affect the safety or effectiveness of the device.

	Primary Predicate Device: EasyDiagnost Eleva (K031535)	***Proposed Device: CombiDiagnost R90 (K163210)***	***Discussion***
Picture archiving and communication system	Yes	Same	Equivalent: No effect on the safety or effectiveness of the device.
Image chain (fluoroscopy)	Philips Image Intensifier / CCD TV / Digital Imaging	Philips dynamic Eleva Image Chain	The proposed *CombiDiagnost R90* includes the cleared Philips *Eleva WorkSpot of the reference device* (K153318) as part of the image chain. Therefore, no effect on the safety or effectiveness of the device
Detector	Image Intensifier 23 cm, 31 cm or 38 cm	Pixium FE 4343F (cleared via K080859 – Villa Sistemi Medicali S.p.A.)	No impact on the safety or effectiveness of the device. The detector data is from the reference device Philips *Eleva WorkSpot* (K153318)
Generator	Philips Velara RF 50kW, 65kW or 80kW	Philips Velara 65kW, optional 80 kW	Equivalent; The proposed *CombiDiagnost R90* uses a Philips generator that operates in the same manner.
Tube	Philips SRO 2550 or SRM 2250 GS	Philips SRO 33100 ROT 380 or SRM 0608 ROT GS 505	Equivalent; The proposed *CombiDiagnost R90* uses Philips tubes that operate in the same manner.
System Control	Near by	Remote	The proposed *CombiDiagnost R90* uses a remote system control. This does not affect the safety and effectiveness.
Indications for Use	The Philips EasyDiagnost Eleva intended use is for the following applications: As a multi-functional/ universal system, general R/F, Fluoro-scopy, Radiography and Angiography can be performed along with pediatric examinations and some more specialized interventional applications.	*CombiDiagnost R90* is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.	Equivalent; The Indications for Use for the proposed *CombiDiagnost R90* is more general in nature.

Summary of Non-Clinical Data:

This 510(k) premarket notification contains technical documentation which includes non-clinical verification and validation tests as well as image quality testing. Tests were performed on the proposed *CombiDiagnost R90* according to the following international and FDA-recognized consensus standards:

- ISO 14971, Medical devices. Application of risk management to medical devices
- IEC 60601-1, Medical electrical equipment. General

requirements for safety. Collateral standard. Safety requirements for medical electrical systems

- IEC 60601-1-2, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- IEC 60601-1-3, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54, Medical electrical equipment. Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62220-1, Medical electrical equipment. Characteristics of digital X-ray imaging devices. Determination of the detective quantum efficiency
- IEC 62304, Medical device software. Software life-cycle processes

The test results demonstrate that the proposed *CombiDiagnost R90* meets the acceptance criteria and is adequate for its intended use.

Based upon the same intended use, similar technology, software functionalities, same product configuration and administration, and similarity of materials, it can be concluded the proposed *CombiDiagnost R90* is substantially equivalent to the primary predicate device EasyDiagnost Eleva, in terms of intended use, design characteristics, and safety and effectiveness.

Summary of Clinical Data:

The proposed *CombiDiagnost R90* did not require a clinical study since substantial equivalence to the currently marketed and predicate device was demonstrated with the following attributes:

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

Substantial Equivalence Conclusion:

The comparison of technological characteristics, non-clinical performance data, safety testing, software validation, and clinical image concurrence data demonstrates that the device is as safe and effective as the predicate device. Philips Medical Systems concludes that the proposed *CombiDiagnost R90* is substantially equivalent to the legally marketed primary predicate device, EasyDiagnost Eleva.