Philips Medical Systems DMC GmbH
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

December 3, 2020

Re: K203087
Trade/Device Name: CombiDiagnost R90
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, KPR, MQB
Dated: November 23, 2020
Received: November 24, 2020

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203087

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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510(k) Summary of Safety and Effectiveness

510(K) Number : K203087

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

Issue Date:	July 17th, 2020	
Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment registration number: 3003768251	
Contact Person:	Dr. Supriya A. Dalvi Regulatory Operations Specialist Phone: +91 9825604544 / +91 8733918445 Fax: +49 40 5078-2425 E-mail: supriya.dalvi@philips.com	
Device Trade 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 Code:	KPR, MQB
Predicate Device:	Trade Name:	*CombiDiagnost R90*
	Manufacturer:	Philips Medical Systems DMC
	510(k) Clearance:	K163210 – January 31, 2017
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR 892.1650
	Classification Panel:	Radiology

	Device Class:	Class II
	Primary Product Code:	JAA
	Secondary Product Codes:	KPR, MQB
Reference Device:	Trade Name:	*DigitalDiagnost C90*
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K202564 - September 30, 2020
	Classification Name:	Stationary x-ray system
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code:	MQB, KPR, LLZ

Device Description:

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

The CombiDiagnost R90 is a remote-controlled fluoroscopy system in combination with high-end digital radiography. The system is suitable for routine X-ray examinations and special examinations on patients in standing, seated or lying positions. The CombiDiagnost R90 retrieves images by means of a Cesium Iodide flat panel detector.

Philips fluoroscopy systems (standard configuration) consist of the Basic unit ("geometry" or "table unit"), Workstation Eleva Workspot (with integrated generator control, hand switch, keyboard, mouse, touch screen and PC), dual screen-monitor, Spot film device (digital camera or flat panel detector), Dynamic detector, Fixed detector, X-ray Generator Velara, X-ray tube assembly, Receptor (Flat panel detector). The optional component like Skyplate wireless portable detectors small and large, Ceiling Suspension (CSM3), Vertical Wall stand (VS2), Ceiling Suspension for monitors, monitor trolley, Remote control for RF viewer, accessories for "Stitching on the Table", are also available.

The Eleva software of the proposed CombiDiagnost R90 is based on a workstation i.e. Eleva Workspot (computer, keyboard, display and mouse) that is used by an operator to preset examination data and to generate, process and handle digital x-ray images. As part of the radiographic system, the Eleva software is intended to acquire, process, store, display and export digital Fluoroscopy and radiographic images.

The Eleva Software system is decomposed into software components. These components are clustered in three component collections like the image handling focused Back-end (BE), the acquisition focused Front-end (FE) and Image Processing (IP).

- The Front-end Software is intended to acquire images.
- The Back-end Software is intended to query patient data from Radiology Information System (RIS), store, display and export digital radiographic images to Picture Archiving and Communication System (PACS)
- The Image Processing Software is intended to perform the pre and post processing on the acquired raw images.

The **CombiDiagnost R90** uses the same workflow from the currently marketed and predicate device, *CombiDiagnost R90 (K163210)* with only the following modifications:

- additional optional components (like the reference monitor, remote control),
- Eleva Workspot updated to incorporate new imaging features mainly from the previously approved reference device, *DigitalDiagnost C90* (K202564) along with functional clusters like Digital Subtraction Imaging and stitching on the table
- updates to improve usability and serviceability.

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:

The **CombiDiagnost R90** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate device, *CombiDiagnost R90 (K163210)*, with regards to the functionality of all its components with the same high voltage generator, X-ray tube, Collimator, Wireless portable detectors, workstation (ELEVA) for images post-processing, storage and viewing. Many of the modifications to the **CombiDiagnost R90** are already FDA cleared in reference device, *DigitalDiagnost C90* (K202564). All features characteristics that potentially have an influence on image quality are assessed and verified according to FDA Guidance for Industry and Food and Drug Administration Staff: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices; issued on September 1, 2016. Further the Non-clinical information sufficiently supports the substantial equivalence as per chapter VII- Non clinical Considerations of FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

These modifications have been evaluated in safety risk assessment report. The risks associated with these changes are considered in the risk management report and risk management activities show that all risks are sufficiently mitigated and that the overall residual risks are acceptable.

The outcome of this technological characteristics comparison between the **CombiDiagnost R90** and currently marketed and predicate device, *CombiDiagnost R90 (K163210)* also demonstrate that the minor differences in the technological characteristics do not affect the safety or effectiveness of the **CombiDiagnost R90** when compared to the currently marketed predicate.

Summary of technological characteristics:

The **CombiDiagnost R90** has the same indications for use and technological characteristics as the currently marketed and predicate device, *CombiDiagnost R90 (K163210)* demonstrating its substantial equivalence to the predicate device. Refer Table 1 below for comparisons of the technological characteristics of **CombiDiagnost R90** and the predicate device and Table 2 for comparison between **CombiDiagnost R90** and the reference device, *DigitalDiagnost C90 (*K202564*)*

Table 1: Comparison of the Technological Characteristics and Indications for use of the **CombiDiagnost R90** and the Currently Marketed and Predicate device, *CombiDiagnost R90*

	Predicate device: CombiDiagnost R90 *(K163210)*	***CombiDiagnost R90***	***Discussion***
Regulation number	21CFR 892.1650	Identical	-
Classification Panel	90 – Radiology	Identical	-
Device Class	Class II	Identical	-
Product codes	JAA, KPR, MQB	Identical	-
Table Features			
Working height (table top center to floorplate)	65 cm – 133 cm	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table tilt movement	-90° to +90°	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table top suspension	Two sides suspensions	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table top material	Plastic laminate or carbon fiber	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table top movement	Lateral: 32 cm (12.6") (± 16 cm (6.3")) Longitudinal: Only detector movements to improve patient comfort	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table top absorption	Plastic, with Carbon fiber: 0.6mm Al @ 100kV, HVL = 3.6mm Al	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Maximum patient weight	284 kg (626 lbs)	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Lateral scan distance	32 cm ± 16 cm	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Lateral scan speed	5 cm/s, soft start and stop Auto centering	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.

Longitudinal scan distance	148 cm (58.3") longitudinal, motorized	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Longitudinal scan speed / Detector movement	3 cm – 20 cm / sec	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Table column angulation	-40° to +40°	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Source image distance	113cm – 183cm	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Collimator	Motorized automatic collimation	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Preparation time for exposure	1 sec (approximately)	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Grid	Parkable	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Auto Grid Selection	Yes	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Automatic pre-position of the table	Yes	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Picture archiving and communication system	Yes	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Image chain (fluoroscopy)	Philips dynamic Eleva Image Chain	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Detector	Pixium FE 4343F (cleared via K080859 – Villa Sistemi Medicali S.p.A.)	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Generator	Philips Velara 65kW, optional 80 kW	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
Tube	Philips SRO 33100 ROT 380 or SRM 0608 ROT GS 505	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.
System Control	Remote, optional nearby with nearby control trolley	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device
Image Acquisition	Eleva WorkSpot	Updated Eleva WorkSpot to include new imaging features UNIQUE 2 and Bone Suppression from the reference device, *DigitalDiagnost C90* (K202564) along with functional clusters, Digital	The basis and functionality of the Image acquisition remains same. The Eleva software is upgraded to incorporate the new features for better imaging was tested and verified to have no impact on the safety or effectiveness of

		Subtraction Imaging and stitching on the table	the device. Thus demonstrating Substantial Equivalence
Operating System	Microsoft Windows 7	Microsoft Windows 10	The upgrade to Window 10 is a part of routine software upgrade done by Microsoft. Further verification tests demonstrates no impact on the safety and effectiveness of the device. Thus demonstrating Substantial Equivalence
Image Processing	UNIQUE (fluoroscopy + radiography modality)	UNIQUE (fluoroscopy modality only) UNIQUE 2 (radiography modality only)	UNIQUE 2 is only used for radiography workflows for the subject device. It is intended to provide improved image processing, reduced noise, and improved contrast compared to UNIQUE for radiography only. UNIQUE 2 does not replace UNIQUE for fluoroscopy or alter the clinical workflow, hence there is no change to the safety or effectiveness of the device. Both UNIQUE and UNIQUE 2 are embedded in their respective workflows and cannot be used cross-modality.
Reference monitor	No	Yes	The additional reference monitor is made available for the display a reference image in the Control Room and the Examination Room. This does not impact safety and effectiveness of the device. Thus, demonstrating Substantial Equivalence
Firmware for the dynamic detector	No	Yes	This is a service tool to provide functionality to perform firmware updates of the detector. It doesn't impact safety and effectiveness of the device. Thus, demonstrating Substantial Equivalence
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.	Identical	Substantially Equivalent; No impact to safety and effectiveness of the device.

Table 2: Comparison of the Technological Characteristics of the **CombiDiagnost R90** and the reference device, *DigitalDiagnost C90*

	CombiDiagnost R90	***Reference Device DigitalDiagnost C90 (K202564)***	***Discussion***
Image Acquisition	Updated Eleva WorkSpot to include new imaging features UNIQUE 2 and Bone Suppression from the reference device, *DigitalDiagnost C90* (K202564) along with functional clusters, Digital Subtraction Imaging and stitching on the table	Eleva WorkSpot	The basis and functionality of the Image acquisition remains same. The Eleva software is upgraded to incorporate the new features for better imaging was tested and verified to have no impact on the safety or effectiveness of the device.
Operating System	Microsoft Windows 10	Identical	No impact on safety and effectiveness of the device. Further testing has been carried to confirm the safety and effectiveness
Image Processing	UNIQUE 2 (radiography modality only)	UNIQUE 2 (radiography modality only)	No impact on safety and effectiveness of the device as the feature is included only in the radiography workflow of the subject device, which is same as the reference device Further testing has been carried to confirm the safety and effectiveness
Post-processing application	Bone Suppression	Identical	No impact on safety and effectiveness of the device. Further testing has been carried to confirm the safety and effectiveness
Scatter correction	Skyflow Plus	Identical	No impact on safety and effectiveness of the device. Further testing has been carried to confirm the safety and effectiveness
Tube Head	Eleva Tube head with optional live camera package	Identical	No impact on safety and effectiveness of the device. Further testing has been carried to confirm the safety and effectiveness

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 **CombiDiagnost R90** according to the following FDA recognized standards and guidance documents as well as additional non-standard performance tests:

- AAMI ANSI ISO 14971:2007/ (R) 2010, Medical devices. Application of risk management to medical devices
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, 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 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - 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 60601-2-54 Edition 1.1 2015-04 CONSOLIDATED VERSION Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62220-1-1 Edition 1.0 2015-03 Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices, issued September 1, 2016
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 2017

Additional non-standard performance tests have been performed to demonstrate the safety and effectiveness as follows:

- System Verification Test
- Image Quality Test
- Human Factors and Usability Engineering Test

The test results of Non-Clinical testing demonstrate that the **CombiDiagnost R90** meets the acceptance criteria and is adequate for its intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated and overall residual risks are acceptable.

Based on the supporting data provided in this 510(k) premarket notification, the **CombiDiagnost R90** is substantially equivalent to the currently marketed and predicate device, *CombiDiagnost R90 (K163210)* in terms of safety and effectiveness.

Summary of Clinical Data:

The **CombiDiagnost R90** did not require a clinical study since substantial equivalence to the currently marketed and predicate device, *CombiDiagnost R90 (K163210)* was demonstrated with the following attributes:

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

Substantial Equivalence Conclusion:

The comparison of technological characteristics, non-clinical performance data, safety testing demonstrates that **CombiDiagnost R90** is substantially equivalent to the currently marketed and predicate device, *CombiDiagnost R90 (K163210)* and is safe and effective.