Philips Medical Systems DMC GmbH
% Supriya Dalvi
Regulatory Affairs Specialist
Roentgenstrasse 24-26
Hamburg, Hamburg 22335
GERMANY

April 2, 2021

Re: K210692
Trade/Device Name: DigitalDiagnost
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB, LLZ
Dated: March 3, 2021
Received: March 8, 2021

Dear Supriya Dalvi:

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)*
K210692

Device Name
DigitalDiagnost

Indications for Use *(Describe)*
The DigitalDiagnost is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and 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

K210692

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

Preparation Date:	March 3rd 2021	
510(k) Owner:	Philips Medical Systems DMC GmbH Roentgenstrasse 24 22335 Hamburg GERMANY Establishment registration number: 3003768251	
Contact:	Dr. Supriya A. Dalvi Regulatory Operations Specialist Phone: +91 9825604544 / +91 8733918445 Fax: +49 40 5078-2425 E-mail: supriya.dalvi@philips.com	
Proposed Device	Device Name	DigitalDiagnost
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Stationary x-ray system
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Primary Product Code:	KPR
	Secondary Product Codes:	MQB, LLZ
Predicate Device	Device Name	DigitalDiagnost C90 (K202564, cleared September 30th, 2020)
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Stationary X-Ray System
	Classification Regulation:	21 CFR Part 892.1680
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Primary Product Code:	KPR
	Secondary Product Codes:	MQB, LLZ
Reference Device	Device Name	CombiDiagnost R90 (K203087, cleared December 3rd, 2020)
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Image-intensified fluoroscopic x-ray System
	Classification Regulation:	21 CFR Part 892.1650

	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Primary Product Code:	JAA
	Secondary Product Codes:	KPR, MQB
Device Description:	The proposed DigitalDiagnost is a high-end digital radiography system consisting of a height adjustable patient support table and a ceiling suspension consisting of a tube including a control handle used to acquire images with a flat panel fixed RAD detector. Additionally, different vertical stands for the radiography examinations are available. The ceiling suspension can be moved in longitudinal and lateral directions and additionally the tube can be tilted and rotated as well. The system is configured with a Philips x-ray generator and a flat panel fixed RAD detector, Pixium 4343RCE. Together with the tube these components form the radiography Image Chain. The additional option of the portable wireless detector i.e. the SkyPlates family can be used for free exposures as well as in the patient support table or in the vertical stand. The proposed DigitalDiagnost is a modification of the predicate device, DigitalDiagnost C90 (K202564). The modifications include change of colour of the table, stand and ceiling suspension; changes in ceiling suspension, service features and a software update. The changes related to the software updates and service features have been recently cleared in the reference device, CombiDiagnost R90 (K203087).	
Indications for Use:	The DigitalDiagnost is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.	
Fundamental Scientific Technology:	The proposed DigitalDiagnost employs the same basic construction, fundamental scientific technology and workflow as the predicate device, DigitalDiagnost C90 (K202564) with regards to the functionality of all its components. It has the same high voltage generator, X-ray tube, Collimator, detectors, workstation (ELEVA) for images post-processing, storage and viewing. The solid state imaging including the detector for proposed device are same as predicate device (K202564) having the same physical, functional and operational characteristics. Also, other image chain components like X-ray tube and generator, which are used for exposure characteristics and clinical performance evaluation remains same. Hence all the features and characteristics potentially influencing image quality are same as predicate device, in accordance to FDA guidance document '*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*, dated September 1, 2016'. The changes with respect to the predicate device are mainly to accommodate users with a focused need for core functionality, some of the optional features of the predicate device have been replaced or modified to result in the proposed DigitalDiagnost. These changes do not affect the clinical or functional outcome of the device. The modifications have been evaluated per the ISO 14971 risk assessment. Design control and risk management activities show that all risks are sufficiently mitigated and that the overall residual risks are acceptable. Refer Table 1 below for comparison of the technological characteristics of the proposed device and predicate device, DigitalDiagnost C90	

Table 1: Comparison of the technological characteristics of the proposed device and predicate device, DigitalDiagnost C90

	Predicate device, DigitalDiagnost C90 (K202564)	**Proposed device, DigitalDiagnost**
Legal Manufacturer	Philips Medical Systems DMC GmbH	Identical
Classification	Class II per 21 CFR 892.1680, Product codes KPR, MQB LLZ	Identical
Regulation Name	Stationary X-ray system	Identical
Class	II	Identical
Review Panel	Radiology	Identical
Indications for Use	The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost C90 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.	Identical except updated trade name
Principle of Operation	DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radiographic images. It is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography. The system consists of several components that can be combined to create a variety of different Xray configurations.	Identical
Components	Height adjustable table (TH2)	Identical except color of table (Change #1)
	Single side suspended table (TH-S)	Identical except color of table (Change #1)
	Vertical moveable stand (VM)	Identical except color of VM stand (Change #1)
	Fixed Vertical Stand (VS)	Identical except color of fixed vertical stand (Change #1)
	Other components like Fixed RAD Detector, Wireless Static Detector, Generator, Tube	Identical
	Digital wireless flat detector	Identical
	Celling Suspension CSM	Identical except change in color of CSM (Change #1)
Collimator	• Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible	Identical except - no live camera (Change #2) - lasers external to the collimator (Change # 4)

		• With light field indicator • Live Tube Head Camera for patient positioning support • With 2 Lasers (inside the collimator)	
	Tube Head Control	Touch control functionality for tube head operation The User interface on Eleva tube head is touch control. Eleva screen display in the examination room enables the user to use all the control room parameters from examination room as well	Mechanical buttons for tube head operation (Change #3) The User interface on tube head has mechanical buttons. Only few functions can be used on tube head screen in the examination room with help of these mechanical buttons. However, all the functionalities can still be controlled from AWS (Acquisition workstation) in the control room
	Tube Head - control handle	Control handle with flat capacitive smart-sensor for releasing brakes for the CSM movement	Control handle with a mechanical button for releasing brakes for the CSM movement (Change #3)
	Detector calibration filter	Integrated in collimator (0.5 mm Cu + 2 mm Al filter)	External to the collimator (21mm Al filter (Change #4) 21mm Al filter used in the proposed device is equivalent to the 0.5 mm Cu + 2 mm Al filter used in the predicate device.
	Service Features	Monitoring of system parameters is as a part of overall service log	Monitoring of system parameters is a part of overall service log, additionally in the proposed device, a provision is made to allow service personnel to extract logs of defined key system parameters for offline analysis. (Change #5)
		Remote Silent Logfile Export is not present	Remote Silent Logfile Export is present. Service feature to remotely export the log file of a system; Identical to the feature used in the reference device (K203087). (Change #5)
		Configurable Philips Remote Server Upload is not present	Configurable Philips Remote Server Upload is present. Service feature where automatic upload of the log file to the Philips Remote Server shall be configurable via the Service Tool. Identical to the feature used in the reference device (K203087) (Change #5)
		Additional DICOM Information to Support Performance Bridge is not present	Additional DICOM Information to Support Performance Bridge is present.

			Service feature where DICOM data will be used by the PerformanceBridge Data collector tool, which is a customer dashboard for system performance monitoring. Identical to the feature used in the reference device (K203087) (Change #5)
		Eleva Logging HSDP PF1.0	Eleva Logging HSDP PF2.0. Service feature involving update of software logging infrastructure. Identical to the feature used in the reference device (K203087) (Change #5)
	Software	Eleva Software, Version 41	Eleva Software, Version 42 (Change #6) Identical to the software used for radiography in the reference device (K203087).
		Windows 10 Operating system	Identical
	Image processing	Eleva workstation	Identical

The outcome of this technological characteristics comparison and risk assessment demonstrate that the minor differences in the technological characteristics do not affect the safety or effectiveness of the proposed DigitalDiagnost, when compared to the legally marketed predicate device (K202564).

Summary of Non-Clinical and Clinical Performance Data:

This 510(K) premarket notification includes non-clinical verification and validation tests. Tests were performed on the proposed DigitalDiagnost according to the following FDA recognized standards and guidance documents:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Recognition #19-4)
- 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 (Recognition #19-8)
- 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 (Recognition # 12-269)
- IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability (Recognition # 5-89)
- IEC 60601-2-54 Edition 1.1 2015-04, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Recognition # 12-296)
- IEC 62304 Edition 1.1 2015-06, Medical device software - Software life cycle processes (Recognition # 13-79)

- ANSI AAMI ISO 14971: 2007/(R)2010, Medical devices-Application of risk management to medical devices (Recognition # 5-40)
- ISO 10993-1, Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Recognition # 2-258)
- *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*

Refer Table 2 for the non-clinical testing that were performed on the proposed device. Test results demonstrate the proposed DigitalDiagnost meets acceptance criteria and is adequate for its intended use. Risk assessment activities show that the risks are sufficiently mitigated.

Table 2: Testing performed on the Proposed device

Tests	**Protocol**	**Test results**
System Verification testing	Identical to predicate device, DigitalDiagnost C90 (K202564) except for the service features in Change # 5 (Monitoring of key system parameters, Remote Silent Logfile Export, Configurable Philips Remote Server Upload, Additional DICOM Information to Support Performance Bridge and Migrate Eleva software logging platform from HSDP PF1.0 to HSDP PF2.0 APIs). The protocols for these service features are identical to the previously cleared reference device, CombiDiagnost R90 (K203087) except for the service feature 'Monitoring of key system parameters'. The feature 'Monitoring of key system parameters' is newly introduced in the proposed device.	Pass System verification test activities substantiate that the system conforms to the system requirements
Software verification testing		Pass Software verification test activities substantiate that the software conforms to the requirements
Risk control measure verification testing	Identical to Predicate device, DigitalDiagnost C90 (K202564)	Pass. System meets the defined risk control measures
Image quality testing	Identical to Predicate device, DigitalDiagnost C90 (K202564)	Pass. Results demonstrate that the tested equipment complies with the applicable Imaging Performance requirements
Usability Engineering	Identical to Predicate device, DigitalDiagnost C90 (K202564) and in compliance to the FDA consensus standards, IEC 60601-1-6 Edition 3.1 2013-10 (Recognition number 5-89)	Pass. Results demonstrate that the test complies with the usability requirements

	There is no clinical data submitted in this 510(k) premarket notification.
Substantial Equivalence Conclusion:	The comparison of intended use, design features, technological characteristics, non-clinical performance data, and safety testing demonstrates the proposed DigitalDiagnost is substantially equivalent to the manufacturer's legally marketed predicate device (K202564), demonstrating the subject device to be safe and effective.