December 13, 2021

Philips Medical Systems DMC GmbH
% Connie Pascual
Sr. Regulatory Affairs Specialist
Roentgenstrasse 24-26
Hamburg, Hamburg 22335
GERMANY

Re: K212186
Trade/Device Name: Philips Radiology Smart Assistant
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, JAA
Dated: November 12, 2021
Received: November 15, 2021

Dear Connie Pascual:

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)*
K212186

Device Name
Philips Radiology Smart Assistant

Indications for Use *(Describe)*
Philips Radiology Smart Assistant is intended to provide patient positioning feedback using validated 2D X-Ray systems. Philips Radiology Smart Assistant is a software which informs Healthcare Professionals regarding patient positioning quality in accordance with clinical guidelines. Philips Radiology Smart Assistant is not intended for diagnostic purposes. It is not intended to be used as the basis for repeating an image.

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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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:	November 12, 2021	
Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment Registration Number: 3003768251	
Primary Contact Person:	Connie Pascual Regulatory Affairs Manager Phone: +1 (978) 659-2440 E-mail: connie.pascual@philips.com	
Secondary Contact Person:	Ann Lebar Phone: +1 (414) 217-6244 E-mail: ann.lebar@philips.com	
Device Name:	Philips Radiology Smart Assistant	
Classification:	Classification Name:	System, X-Ray, Stationary
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	KPR, JAA
	Trade Name/Device Name:	Philips Radiology Smart Assistant
Primary Predicate Device:	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K210692
	Classification Regulation:	21 CFR Part 892.1680
	Classification Name:	System, X-Ray, Stationary
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	KPR
	Trade Name/Device Name:	DigitalDiagnost

Reference Device:	Manufacturer:	Philips Healthcare Informatics, Inc.
	510(k) Clearance:	K182926
	Classification Regulation:	21 CFR 892.2050
	Classification Name:	System, Image Processing, Radiological
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ
	Trade Name/Device Name:	IntelliSpace Radiology

Device description:

Philips Radiology Smart Assistant is a software package intended to be used by qualified healthcare professionals. The software is used with general purpose computing hardware for the processing, display of images, and patient positioning feedback within a clinical environment. Philips Radiology Smart Assistant software supports receiving and displaying images from X-ray systems.

The system supports receiving, sending, storing, acceptance and displaying of medical images received from the following modality types via DICOM: DX as well as hospital/radiology information systems.

Philips Radiology Smart Assistant includes a post-processing patient positioning feedback function for posterior-anterior (PA) chest X-ray images. The patient positioning assessment is intended to provide a qualified healthcare professional with timely feedback on the quality of acquired X-ray images that do not suffice the positioning quality standards of clinical guidelines. The quality check comprises an assessment of the following parameters:

- Collimation
- Patient Rotation
- Patient Inhalation State

Indications for Use:

Philips Radiology Smart Assistant is intended to provide patient positioning feedback using validated 2D X-Ray systems. Philips Radiology Smart Assistant is a software which informs Healthcare Professionals regarding patient positioning quality in accordance with clinical guidelines. Philips Radiology Smart Assistant is not intended for diagnostic purposes. It is not intended to be used as the basis for repeating an image.

Fundamental Scientific Technology:

The proposed device, Philips Radiology Smart Assistant, is a software accessory to currently marketed parent predicate device, DigitalDiagnost (K210692). This software is used with general purposed computing hardware for the processing and display of images throughout a clinical environment by healthcare professionals. The Philips Radiology Smart Assistant provides post-processing patient positioning feedback for PA chest X-ray images.

At a high level the Philips Radiology Smart Assistant and the parent predicate device (K210692) are based on the following equivalent elements:

- Similar Intended Use
- Prescription Only
- Compatibility with standard radiological images
- Processes and displays digital radiographic images

The following technological differences exist between the proposed and parent predicate device:

- Anatomy of interest is PA chest images only
- Patient Positioning Feedback feature
- Not intended to be used on pediatric population

Summary of technological characteristics:

The presented technological differences are considered low risk, providing additional features such as the Patient Positioning Feedback for the purposes of training and education for healthcare professionals. This new functionality has been verified and validated, and does not raise new questions on safety and/or effectiveness. This new features has not changed the intended use and operational principles of the parent predicate device. Therefore, Philips Radiology Smart Assistant is substantially equivalent to the currently marketed parent predicate device, DigitalDiagnost (K210692).

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the Philips Radiology Smart Assistant and demonstrates compliance with the following international and FDA-recognized consensus standards and FDA guidance document:

- **EN ISO 14971:2012** Medical devices – Application of risk management to medical devices
- **IEC 82304-1:2016** Health Software – General requirements for product safety
- **IEC 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices
- **NEMA-PS 3.1 – PS 3.20** Digital Imaging and Communications in Medicine (DICOM)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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

Non-Clinical verification and or validation test results demonstrate that the Philips Radiology Smart Assistant:

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

Therefore, the Philips Radiology Smart Assistant is substantially equivalent to the primary currently marketed and predicate device, DigitalDiagnost (K210692) in terms of safety and effectiveness.

Summary of Clinical Data:

The Philips Radiology Smart Assistant did require a clinical study based upon the following attributes:

- Main Feature – Patient Positioning Feedback
- Indications for use

Clinical performance testing was conducted on previously acquired posteroanterior (PA) chest X-ray images in order to demonstrate the performance of the Philips Radiology Smart Assistant in providing patient positing feedback. The algorithm's assessment as to whether or not an image met quality criteria for aspects of patient positioning quality was compared to the positioning quality assessment of clinicians using standard diagnostic metrics. The results of the clinical performance study support the performance of the Philips Radiology Smart Assistant in identification of patient positioning quality issues. The clinical performance study demonstrates that the Philips Radiology Smart Assistant is safe and effective for the specified intended use.

Substantial Equivalence Conclusion:

The Philips Radiology Smart Assistant is a software accessary that is substantially equivalent to its predicate parent device, DigitalDiagnost (K210692), in terms of similar intended use and different technological characteristics that do not raise different questions of safety and effectiveness. A clinical performance study was performed to demonstrate the performance of the patient positioning feedback algorithm. 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, IEC 82304, IEC 62366 and EN ISO 14971. The results of these tests demonstrate that Philips Radiology Smart Assistant met the acceptance criteria and is adequate for the specified intended use.