DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PHILIPS MEDICAL SYSTEMS DMC GMBH
MING XIAO
REGULATORY AFFAIRS MANAGER, NORTH AMERICA
ROENTGENSTRASSE 24-26
HAMBURG 22335
DE

July 7, 2017

Re: K171461
Trade/Device Name: SkyPlate Detector for Philips Radiography/Fluoroscopy Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 18, 2017
Received: May 18, 2017

Dear Mr. 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,

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

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)*

K171461

Device Name

SkyPlate Detector for Philips Radiography/Fluoroscopy Systems

Indications for Use *(Describe)*

As a part of a radiographic system, the SkyPlate Detector for Philips Radiography/Fluoroscopy Systems is intended to acquire, process, store, display and export digital radiographic images. The SkyPlate Detector for Philips Radiography/ Fluoroscopy Systems is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, 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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PHILIPS

6. 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:	May 16, 2017 (original Submission Date) July 4, 2017 (Revision)	
Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment registration number: 3003768251	
Contact Person:	Ming Xiao Regulatory Affairs Manager North America Phone: +49 40 5078-2306 Fax: +49 40 5078-2425 E-mail: ming.xiao@philips.com	
Trade / Device Name:	***SkyPlate Detector for Philips Radiography/Fluoroscopy Systems***	
Classification:	(Primary) Regulation Name:	Stationary x-ray system
	(Primary) Regulation Number:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Regulatory Class:	Class II
	(Primary) Product Code:	MQB
	(Secondary) Product Code:	LLZ
	(Secondary) Regulation Name:	Picture archiving and communication system
	(Secondary) Regulation Number:	21 CFR 2050
Predicate Device:	Trade / Device Name:	Philips *Eleva Workspot with SkyPlate Detectors*
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K141736 – July 25, 2014
	Regulation Name:	Stationary x-ray system, Picture archiving and communications system
	Regulation Number:	21CFR 892.1680, 21 CFR 2050

	Classification Panel:	90 -- Radiology
	Device Regulatory Class:	Class II
	Product code:	MQB, LLZ
Reference Device I:	Trade / Device Name:	Philips *CombiDiagnost R90*
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K163210 – January 31, 2017
	Regulation Name:	Image-intensified Radiography/Fluoroscopy x-ray system
	Regulation Number:	21 CFR 892.1650
	Product Code:	JAA, KPR and MQB
	Device Regulatory Class:	Class II
Reference Device II:	Trade / Device Name:	Philips *Eleva Workspot with SkyFlow*
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K153318 – December 22, 2015
	Regulation Name:	Stationary X-ray System
	Regulation Number:	21 CFR 892.1680
	Product Code:	MQB, LLZ
	Device Regulatory Class:	Class II

Device Description:

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is a Solid State X-ray Imaging Device that converts x-ray patterns into electrical signals. The signals are converted into visible images for use in medical diagnosis. A cesium iodide scintillator absorbs the input x-ray photons in the detector. The cesium iodide scintillator in turn emits visible spectrum photons that illuminate an array of photodetectors that create an electrical charge representation of the x-ray input. A matrix scan of the array converts the integrated charges into a modulated electrical signal.

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is optionally installed and is intended to be integrated into an x-ray system, where it constitutes an x-ray receptor for direct radiography x-ray imaging. It is electrically powered by and connected with the x-ray system. The *SkyPlate Detector for Philips*

Radiography/Fluoroscopy Systems is connected to the Philips *Eleva Workspot with SkyFlow* (cleared via K153318) to create a complete x-ray imaging chain, and is intended to be used for radiography in Philips Radiography/Fluoroscopy systems, such as the *CombiDiagnost R90* (cleared via K163210). The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems*, is used to acquire diagnostic radiographic images during radiographic procedures. Key features for the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* are provided below:

- Detector Size:
  SkyPlate Large (also called Pixium 3543EZ):
  384.5mm x 460.5mm x 16mm
  SkyPlate Small (also called Pixium 2430EZ):
  268.5mm x 328.5mm x 16mm
- Image Size:
  SkyPlate Large (also called Pixium 3543EZ):
  2400 x 2880 pixels
  SkyPlate Small (also called Pixium 2430EZ):
  1560 x 1920 pixels
- Pixel Size: 148µm
- Image Resolution up to 3.38 LP/mm

The identical *Skyplate* detector was previously cleared under K141736 (July 25, 2014) for use with currently marketed Philips radiography systems, such as the Philips *DigitalDiagnos*t and the Philips *ProGrade*.

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is integrated for use with Philips radiography/fluoroscopy systems, such as the *CombiDiagnost R90* (K163210). The modifications included mechanical integration of the *SkyPlate* detector and the radiography/fluoroscopy system and integration of the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* software interface with the Philips *Eleva Workspot with SkyFlow* software (K153318) to facilitate communication.

Indications for Use:

The Indication for Use for the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is as follows:

As a part of a radiographic system, the SkyPlate Detector for Philips Radiography/Fluoroscopy Systems is intended to acquire, process, store, display and export digital radiographic images. The SkyPlate Detector for Philips Radiography/Fluoroscopy Systems is suitable for all routine radiography exams, including

specialist areas like intensive care, trauma, or pediatric work, excluding mammography.

Fundamental Scientific Technology:

The fundamental scientific technology of the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is that it converts x-ray patterns into electrical signals, which are then converted into visible images for use in medical diagnosis.

The fundamental scientific technology of the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* remains unchanged from the currently marketed and predicate *Philips Eleva Workspot with SkyPlate Detectors* (K141736, July 25, 2014) thus demonstrating substantial equivalence.

Summary of Non-clinical Performance Data:

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* complies with the following international and FDA-recognized consensus standards:

- International and FDA-recognized consensus standards:
  - ISO 14971: Medical Devices - Application of risk management to medical devices
  - NEMA PS 3.1-3.20 Digital Imaging and Communication in Medicine (DICOM) Set
  - AAMI ANSI IEC 62304:2006 Medical Device Software – Software lifecycle processes
- IEC 62220-1: Medical electrical equipment, Characteristics of digital x-ray imaging devices
  - IEC 62220-1-1:2015: 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 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + A1:2012, MOD)
  - 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 in diagnostic X-ray equipment
- IEC 60601-2-54: Medical electrical equipment. Particular requirements for basic safety and essential performance of

X-ray equipment for radiography and radioscopy

- Device specific guidance document:
  - "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Device", issued September 1, 2016
  - "Guidance for the Content of Premarket Submissions for software contained in Medical Device", issued May 11, 2005
  - Pediatric information for X-Ray Imaging Device Premarket Notifications, Draft, issued May 10, 2012

Non-clinical verification and validation tests have been performed with regards to the intended use, technical claims, requirement specifications, and risk management results. The software information was provided according to a moderate level of concern.

Non-clinical verification and validation test results demonstrate that the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems:*

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

Therefore, the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is substantially equivalent to the currently marketed and predicate *Philips Eleva Workspot with SkyPlate Detectors* (K141736, July 25, 2014) thus demonstrating substantial equivalence.

Summary of Clinical Data:

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* 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

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, as

Conclusion:

effective, and performs as well or better than the predicate device.

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* has the same indications for use and intended use, has identical or equivalent technological characteristics, provides images of equivalent diagnostic capability, and does not introduce new potential hazards or safety risks.

The *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* is substantially equivalent to the currently legally marketed predicate device (K141736, July 25, 2014) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. 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: IEC 62304 and ISO 14971. The results of these tests demonstrate that the *SkyPlate Detector for Philips Radiography/Fluoroscopy Systems* met the acceptance criteria and is adequate for its intended use.