DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2017

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

Re: K170113
Trade/Device Name: pixium 4343RCE
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 13, 2017
Received: January 17, 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

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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)*
K170113

Device Name
pixium 4343RCE

Indications for Use *(Describe)*
As a part of a radiographic system, the Pixium 4343RCE is intended to acquire digital radiographic images. The Pixium 4343RCE is suitable for all routine radiography exams, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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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:	February 03, 2017	
Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment registration number: 3003768251	
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:	***pixium 4343RCE***	
Classification:	Classification Name:	Stationary x-ray system,
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code:	MQB
Predicate Device:	Trade Name:	Philips *pixium* 4343RC
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K131483 – October 07, 2013
	Classification Name:	Stationary x-ray system
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code:	MQB

Device Description:

The *pixium 4343RCE* is a Stationary x-ray system that converts x-ray patterns into electrical signals. The signals are converted into visible images for use in medical diagnosis. In the device, a cesium iodide scintillator absorbs the input x-ray photons. The 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 detector is permanently installed and intended to be integrated into an x-ray system, where it constitutes an x-ray receptor for direct x-ray imaging. It is electrically powered by and connected with the x-ray system. The device is connected to the Philips *Eleva Workspot* to create a complete x-ray imaging chain, and it is intended to be used in Philips x-ray systems such as the *DigitalDiagnost*.

- Detector Size: 500 x 490 x 45 mm^3
- Image Size (Pixel): 2840 x 2874
- Pixel Size: 148 µm
- Image Resolution up to 3.4 LP/mm

A similar detector (*pixium 4343RC*) has received pre-market clearance under K131483 (October 7, 2013), for use with the following currently marketed Philips x-ray systems:

- Philips *DigitalDiagnost* (K141736 – July 25, 2014),
- Philips *Eleva Workspot* (K153318 – Dec 22, 2015)

Description of Modification

The modifications are restricted to the mechanical integration of the *pixium 4343RCE* into the Philips *DigitalDiagnost* x-ray system, slight electronic modifications inside the detector, and adaptation of the proposed *pixium 4343RCE* x-ray detector software interface with the Philips *Eleva Workspot with SkyFlow* software to facilitate communication. The mechanical integration into the Philips *DigitalDiagnost* system consists of a minor modification to the Bucky trays for the x-ray table *DigitalDiagnost TH2* and the vertical wall stands *DigitalDiagnost VM* and *Bucky Diagnost VS.* The electrical integration consists of a new power supply (*safety extra low voltage*) for the detector, and a new interface connector for the detector.

Note: the *pixium 4343RCE* is only intended to be integrated with the Philips *DigitalDiagnost* x-ray system and the Philips *Eleva Workspot with SkyFlow*.

These changes do not raise any new questions on safety or efficacy. In particular, these changes do not necessitate nor cause any modifications to the following:

- the x-ray tube,
- the x-ray generator,
- the anti-scatter grid,
- the x-ray control, or
- the collimator of the Philips *DigitalDiagnost* system.

Comparison of the currently marketed and predicate *pixium 4343RC* versus the proposed *pixium 4343RCE*			
	Predicate Device pixium 4343RC (K131483)	***Proposed Device pixium 4343RCE*** (K170113)	***Discussion***
Design Features			
X-Ray Absorber	CsI Scintillator	CsI Scintillator	Identical; no impact to safety and effectiveness.
Installation type	Stationary, permanently installed	Stationary, permanently installed	Identical; no impact to safety and effectiveness.
Readout Mechanism	Thin Film Transistor	Thin Film Transistor	Identical; no impact to safety and effectiveness.
Detector Size	500 x 490 x 45.5 mm^3	500 x 490 x 45 mm^3	Similar, proposed detector has a slightly smaller detector size however, there is no impact to safety or effectiveness.
Detector Weight	<14 kg	11.7kg ± 0.85kg	Similar, proposed detector is slightly lighter however, there is no impact to safety or effectiveness.
Image Size (Pixel)	2840 x 2874	2840 x 2874	Identical; no impact to safety and effectiveness.
Image Size (X-ray field)	420 x 425 mm^2	420 x 425 mm^2	Identical; no impact to safety and effectiveness.
Distance Image to Rim	34.9 mm	40mm	Similar, proposed detector has a slightly greater distance image to rim however, there is no impact to safety or effectiveness.
Pixel Size	148µm	148µm	Identical; no impact to safety and effectiveness.
Nyquist Frequency:	3.37 lp/mm	3.37 lp/mm	Identical; no impact to safety and effectiveness.
ADC Digitization	16 bit	16 bit	Identical; no impact to safety and effectiveness.
Signal to Electronic Noise Ratio (SENR)	42.3 dB (@ 1 µGy)	42.3 dB (@ 1 µGy)	Identical; no impact to safety and effectiveness.
Maximum X-ray Dose for Linear Response	50 µGy	50 µGy	Identical; no impact to safety and effectiveness.
Image Readout Duration	1.6 s	1.36 s	The image readout duration is slightly faster and therefore does not impact safety and effectiveness.
Number of Modes	2	3	An additional default mode is included with the proposed detector. There is no impact safety and effectiveness.

Comparison of the currently marketed and predicate *pixium 4343RC* versus the proposed *pixium 4343RCE*			
	Predicate Device pixium 4343RC (K131483)	***Proposed Device pixium 4343RCE*** (K170113)	***Discussion***
Exposure Window Durations	1-8192 ms	0-8191 ms	Similar, proposed detector has a minimal decrease in the exposure window duration, however it is insignificant and thus there is no impact to safety or effectiveness.
Sequence Time Detector	6 s	6 s	Identical; no impact to safety and effectiveness.
Image Data	16.3 MBytes	16.3 MBytes	Identical; no impact to safety and effectiveness.
Use w and w/o Radiographic Grid?	Yes	Yes	Identical; no impact to safety and effectiveness.
Maximum Lifetime Dose	100 Gy	100 Gy	Identical; no impact to safety and effectiveness.
Warm-up Duration before Calibration	4 h	2 h	The warm-up duration before calibration has been decreased, thus there is no impact to safety or effectiveness.
Digital Sub-traction Angio-graphy (DSA)	None (exempt from intended use)	None (exempt from intended use)	Identical; no impact to safety and effectiveness.
Positioning Mode	None	None	Identical; no impact to safety and effectiveness.
Stitching Mode (Implemented in Detector)	None	None	Identical; no impact to safety and effectiveness.
Binning	None (1 x 1)	None (1 x 1)	Identical; no impact to safety and effectiveness.
Framespeed: Dynamic Imaging – Pulsed	None	None	Identical; no impact to safety and effectiveness.
Data Interface to Workstation	100 Mbit/s Ethernet	1 Gbit/s Ethernet	The data interface to workstation has been increased. There is no impact to safety or effectiveness.
Power Consumption	20.4W	Avg: 8W, Max: 15W	The power consumption has been decreased. There is no impact to safety or effectiveness.
Cover Factor (Optical Fill Factor)	60.3%	63%	Similar, the cover factor is essentially the same and thus there is no impact to safety or effectiveness.

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Comparison of the currently marketed and predicate *pixium 4343RC* versus the proposed *pixium 4343RCE*			
	Predicate Device ***pixium 4343RC*** (K131483)	***Proposed Device*** ***pixium 4343RCE*** (K170113)	***Discussion***
Modulation Transfer Function (MTF)	1 lp/mm 64% 2 lp/mm 32% 3 lp/mm 17% Nyquist 13% (3.37 lp/mm)	1 lp/mm 62% 2 lp/mm 35% 3 lp/mm 19% Nyquist 15% (3.37 lp/mm)	Similar, the MTF has remained essentially the same, with some improvements and one very minimal decrease, thus, overall, there is no impact to safety and effectiveness.
Detective Quantum Efficiency (DQE)	DQE at 2 µGy lp/mm % 0.05 65 1 52 2 42 3 25 3.37 18	DQE at 2 µGy lp/mm % 0.05 67 1 51 2 42 3 27 3.37 18	Similar, the DQE has remained essentially the same, with one improvement and one very minimal decrease, thus, overall, there is no impact to safety and effectiveness.
Image Processing	*XD-S Eleva Workstation* (previously "*XD-S Direct Workstation/Package*") (K063781) UNIQUE also: UM, DRR, and UNIQUE for PCR storage phosphor cassettes	Philips *Eleva WorkSpot with SkyPlate (K153318)* UNIQUE also: UM, DRR, and UNIQUE for PCR storage phosphor cassettes	Similar; The *Eleva WorkSpot with SkyPlate* is a cleared device. There is no impact to safety and effectiveness.
Grid line suppression	Mechanical Grid Oscillation or Image Pre-Processing ("*Grid Suppression*")	Mechanical Grid Oscillation or Image Pre-Processing ("*Grid Suppression*")	Identical; no impact to safety and effectiveness.

Indications for Use:

The Indication for Use for the *pixium 4343RCE* is as follows:

As a part of a radiographic system, the pixium 4343RCE is intended to acquire digital radiographic images. The pixium 4343RCE is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

Fundamental Scientific Technology:

The fundamental scientific technology of the *pixium 4343RCE* is that it is a device that converts x-ray patterns into electrical signals, which are then converted into visible images for use in medical diagnosis.

Based on the information provide above, the basic fundamental scientific technology of the *pixium 4343RCE* remains unchanged from the currently marketed and predicate *pixium* 4343RC (K131483, October 7, 2013) thus demonstrating substantial equivalence.

Summary of Non-clinical Performance Data:

The *pixium 4343RCE* 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 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- Device specific guidance document:
  - "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Device (September 1, 2016)"
  - "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11th, 2005)"

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 for the *pixium 4343RCE* is of a moderate level of concern. Software documentation in support of a moderate level of concern, as outlined in the FDA's software guidance has been provided in the premarket notification.

Non-clinical verification and validation test results demonstrate that the *pixium 4343RCE:*

- Complies with the aforementioned international and FDA-recognized consensus standards and device specific guidance document entitled "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Device (September 1, 2016)"
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the *pixium 4343RCE* is substantially equivalent to the currently marketed and predicate *pixium 4343RC* (K131483, October 7, 2013) thus demonstrating substantial equivalence.

Summary of Clinical Data:

The *pixium 4343RCE* 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, as effective, and performs as well or better than the predicate device.

The *pixium 4343RCE* 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 *pixium 4343RCE* is substantially equivalent to the currently legally marketed predicate device (K131483, October 7, 2013) 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 *pixium 4343RCE* met the acceptance criteria and is adequate for its intended use.