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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.

Manufacturer:	Philips Medical Systems DMC GmbH Roentgenstrasse 24-26 22335 Hamburg GERMANY Establishment registration number: 3003768251
Contact Person:	Gerold Schwarz Q&R Segment Lead Radiography/Fluoroscopy Phone: +49 40 5078-1116 Fax: +49 40 5078-2022 E-mail: gerold.schwarz@philips.com.
Device Name:	**Philips *Eleva Workspot with SkyPlate Detectors***

Classification:

(Primary) Product code	MQB
(Primary) Classification Name:	Stationary x-ray system
(Primary) Classification Regulation:	21CFR 892.1680
(Secondary) Product code:	LLZ
(Secondary) Classification Name:	Picture archiving and communications system
(Secondary) Classification Regulation:	21 CFR 892.2050
Classification Panel:	Radiology
Device Class:	Class II

Predicate Device:

Trade Name: (Primary predicate device)	Philips Eleva Workspot
Manufacturer:	Philips Medical Systems DMC GmbH
510(k) Clearance:	K140771; April 25, 2014
Product codes	MQB, LLZ
Classification Names:	Stationary x-ray system, Picture archiving and communications system
Classification Regulations:	21CFR 892.1680, 21 CFR 892.2050
Trade Name: (Secondary predicate device)	Wireless Portable Detector FD-W17
Manufacturer:	Philips Medical Systems DMC GmbH
510(k) Clearance:	K090625, March 24, 2009
Product code	MQB

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Classification Name: | Stationary x-ray system
Classification Regulation: | 21CFR 892.1680

Device description: The **Philips *Eleva Workspot with SkyPlate Detectors*** is a workstation (computer, keyboard, display, mouse), introducing the new flat solid state X-ray detectors "*SkyPlate*". It is used by the operator to generate, process and handle digital X-ray images. There are two different product configurations of the **Philips *Eleva Workspot with SkyFlow Detectors*: Philips *ProGrade*, and Philips *Eleva Workspot for DigitalDiagnost*.** The **Philips *ProGrade*** is used as a retrofit upgrade for the Philips *BuckyDiagnost* (K945278), whereas the **Philips *Eleva Workspot for DigitalDiagnost*** integrates a new generation of wireless portable x-ray detectors (*SkyPlate*) to replace the x-ray detector WPD FD-W17 (K090625) within the **Philips *DigitalDiagnost*** radiography system.

Indications for Use: The Indication for Use of the **Philips *Eleva Workspot with SkyFlow Detectors*** is identical to that of the currently marketed and predicate device, Philips *Eleva Workspot*, (cleared in K140771, April 25, 2014), and is as follows:

As a part of a radiographic system, the **Philips *Eleva Workspot with SkyFlow Detectors*** is intended to acquire, process, store, display, and export digital radiographic images. The **Philips *Eleva Workspot with SkyPlate Detectors*** 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 **Philips *Eleva Workspot with SkyFlow Detectors*** employs the same basic construction and fundamental scientific technology as provided with the currently marketed and primary predicate device, Philips *Eleva Workspot* (cleared in K140771, April 25, 2014), with regards to the functionality of the following: image receptor type, image processor, automatic image processing, manual image processing, advanced image processing, image export (interfaces), and the use of standard monitors. The new *SkyPlate* detectors employ the same basic construction and fundamental scientific technology as provided with the currently marketed and secondary predicate device Wireless Portable Detector FD-W17 (cleared in K090625, March 24, 2009).

Based on the information provided above, the **Philips *Eleva Workspot with SkyFlow Detectors*** is considered substantially equivalent to the currently marketed and predicate device, Philips *Eleva Workspot,* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data: The non-clinical performance testing constrains that the main physical values for comparison of X-ray devices like DQE and MTF are basically equal or better than the predicate device ranging from 61% to 14% for MTF (predicate 60% to 15%) and from 66% to 24% for DQE (predicate 66% to 22%).

The non-clinical performance data demonstrate substantial equivalence. They include (but are not limited to):

> Detective Quantum Efficiency (DQE)
> Modulation Transfer Function (MTF)
> Aliasing
> Output signal level
> Lag, Memory Effects and Ghost Images
> Allowable types and quantity of defects
> Change in detection sensitivity
> Latent image decay characteristic
> Recovery time for radiographic devices
> Dose requirements and reciprocity changes
> Stability of device characteristics
> Uniformity of device characteristics
> Reuse rate for radiographic devices
> Test pattern image tests

The **Philips *Eleva Workspot with SkyFlow Detectors*** complies with the following international and FDA-recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes
- AAMI/ANSI IEC 62366 Application of usability engineering to medical devices
- ISO 14971 Application of risk management to medical devices
- ANSI/AAMI ES60601-1 Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-3 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 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 ME equipment - Part 1-2: Determination of the detective quantum efficiency
- NEMA PS 3.1 - 3.20 Digital Imaging And Communications In Medicine (DICOM) Set
- ISO 10993-1 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

Non-clinical software verification and validation tests have been performed with regards to the intended use, technical claims, requirements specifications and risk management results.

The non-clinical software verification and validation test results demonstrate that the **Philips *Eleva Workspot with SkyFlow Detectors*** complies with international and FDA-recognized consensus standards and meets the acceptance criteria and is adequate for its intended use. Therefore, the

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Philips *Eleva Workspot with SkyPlate Detectors* is substantially equivalent to the currently marketed device, Philips *Eleva Workspot (K140771; 25 April 2014)* combined with Philips *Wireless Detector FD-W17 (K090625; 24 March 2009)* in terms of safety and effectiveness.

Summary of Clinical Data:

A single-blinded concurrence study according to CDRH's *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices* was conducted, and the study confirmed that the new x-ray detectors *SkyPlate* provide images of equivalent diagnostic capability to the predicate device, the Philips WPD FD-W17, and its results demonstrate substantial equivalence.

Substantial Equivalence Conclusion:

The **Philips *Eleva Workspot with SkyPlate Detectors*** is substantially equivalent to the currently marketed and predicate device (*Philips Eleva Workspot K140771* using the Philips *Wireless Detector FD-W17, K090625*) 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, IEC 62366, ISO 14971, ES60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54, IEC 62220-1, and NEMA PS 3.1 - 3.20.

The results of these tests demonstrate that **Philips *Eleva Workspot with SkyPlate Detectors*** the acceptance criteria and are adequate for this intended use. 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 devices.

July 25, 2014

Philips Medical Systems DMC GmbH
% Mr. Gerold Schwarz
Q&R Segment Lead Radiography/Fluoroscopy
Roentgenstrasse 24-26
Hamburg, 22335
GERMANY

Re: K141736
       Trade/Device Name: Philips ProGrade; Philips Eleva Workspot for DigitalDiagnost
       Regulation Number: 21 CFR 892.1680
       Regulation Name: Stationary x-ray system
       Regulatory Class: II
       Product Code: MQB, LLZ
       Dated: June 24, 2014
       Received: June 27, 2014

Dear Mr. Schwarz:

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.

Page 2—Mr. Schwarz

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

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
 and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K141736

Device Name
Philips Eleva Workspot with SkyPloate Detectors

Indications for Use *(Describe)*
As a part of a radiographic system, the Philips Eleva Workspot with SkyPlate Detectors is intended to acquire, process, store, display, and export digital radiographic images. The Philips Eleva Workspot with SkyPlate Detectors 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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