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 Specialist, North America
Roentgenstrasse 24-26
Hamburg, 22335, DE

December 22, 2015

Re: K153318
Trade/Device Name: Philips Eleva Workspot With Skyflow
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: November 13, 2015
Received: November 18, 2015

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

PHILIPS

6. 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)*
K153318

Device Name
Philips Eleva Workspot with SkyFlow

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

PHILIPS

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. Preparation date of the initial summary is November 11th, 2015.

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:	***Philips Eleva Workspot with SkyFlow***	
Classification (primary):	Classification Name:	Stationary x-ray system
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	MQB (Solid State X-Ray Imager)
Subsequent Product Code :	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21CFR 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	LLZ (system, image processing)
Predicate Device:	Trade Name:	Philips *Eleva Workspot*
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K140771 – March 21, 2014

PHILIPS

Classification Name:	Picture archiving and communications system
Classification Regulation:	21 CFR 892.1680
Classification Panel:	Radiology
Device Class:	Class II
Primary Product code:	MQB (Solid State X-Ray Imager)
Subsequent Product Code:	LLZ (system, image processing)

Device description:

The Philips *Eleva Workspot with SkyFlow* is a workstation (computer, keyboard, display, mouse), combined with a flat solid state X-ray detector. It is used by the operator to preset examination data and to generate process and handle digital X-ray images. The Philips *Eleva Workspot with SkyFlow* will be used as a common software platform in the following currently marketed Philips X-ray systems:

- Philips *Digital Diagnost* (K131483 – October 7, 2013),
- Philips *MobileDiagnost* (K111725 – July 19, 2011),
- Philips *PCR Eleva* (K093355– October 28, 2009),
- Philips *EasyDiagnost Eleva (K031535 – September 6, 2006), and*
- Philips *BuckyDiagnost (K945278 – December 29, 1994).*

As a part of a radiographic system, the Philips *Eleva Workspot with SkyFlow* is intended to acquire, process, store, display, and export digital radiographic images. The Philips *Eleva Workspot with SkyFlow* is intended for clinical situations where practitioners deem necessary to remove the anti-scatter grid in critical care departments of hospitals (such as ICU and Emergency), where patients require portable radiographs. Whereas the Pre-Market Notification K140771 of the predicate device limited the indications for use of the SkyFlow option to bedside chest exams only, this Pre-Market Notification covers also other anatomical regions where scattered radiation might have an impact on image quality.

There is a standalone version with minimal integration into the X-ray system. With the fully integrated version, the workstation screen also provides displays area and controls for X-ray generator control. The workstation computer can also host parts of the system control software.

Indications for Use:

The Indication for Use of the Philips *Eleva Workspot with SkyFlow* is identical to that of the currently marketed and predicate device, Philips *Eleva Workspot* K140771 – March 21, 2015, and is as follows:

> *As a part of a radiographic system, the* Philips *Eleva Workspot with SkyFlow is intended to acquire, process, store, display, and export digital radiographic images. The* Philips *Eleva Workspot with SkyFlow 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* employs the same basic construction and fundamental scientific technology as provided with the currently marketed and predicate device, Philips *Eleva Workspot* K140771 – March 21, 2015, 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), X-ray generator integration and the use of standard monitors.

Based on the information provided above, the ***Philips Eleva Workspot with SkyFlow*** is considered substantially equivalent to the currently marketed and predicate device, Philips *Eleva Workspot* K140771 – March 21, 2015, in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

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

- IEC 62304 *Medical device software – Software life cycle processes* (2006)
- IEC 62366-1 Edition 1.0 2015-02, *Medical Device* – Part 1: *Application of usability engineering to medical devices* (2015)
- ISO 14971 *Application of risk management to medical devices* (2007)

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* complies with international and FDA-recognized consensus standards and meets the acceptance criteria and is adequate for its intended use. Therefore, the Philips *Eleva Workspot with SkyFlow* is substantially equivalent to the

currently marketed device, Philips *Eleva Workspot* K140771 – March 21, 2015, in terms of safety and effectiveness.

The image quality test results were equivalent or better with the modified SkyFlow function turned on than with this function turned off.

Summary of Clinical Data:

The Philips *Eleva Workspot with SkyFlow* did not require clinical studies 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.

Summary of Substantial Equivalence Conclusion:

The Philips *Eleva Workspot with SkyFlow* is substantially equivalent to the currently marketed and predicate device, Philips *Eleva Workspot*, K140771 – March 21, 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, IEC 62366 and ISO 14971. The results of these tests demonstrate that Philips *Eleva Workspot with SkyFlow* met the acceptance criteria and is adequate for this intended use.