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

October 18, 2016

PHILIPS MEDICAL SYSTEMS NEDERLANDS B.V.
C/O MARK JOB
RESPONSIBLE THIRD PARTY OFFICIAL
1394 25TH STREET, NW
BUFFALO MN 55313

Re: K162025
Trade/Device Name: IntelliSpace Portal Platform
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 7, 2016
Received: October 11, 2016

Dear Mr. Job:

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

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)*
K162025

Device Name
IntelliSpace Portal Platform

Indications for Use *(Describe)*
Philips IntelliSpace Portal Platform is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network.
The system allows networking, selection, processing and filming of multimodality DICOM images.
This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications .
Philips IntelliSpace Portal Platform is intended to be used by trained professionals, including but not limited to physicians and medical technicians.
This medical device is not to be used for mammography.
The device is not intended for diagnosis of lossy compressed images.

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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510(k) Summary

IntelliSpace Portal Platform

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date prepared:	September 18, 2016

I. Submitter's name and address

Establishment name:	Philips Medical Systems Nederland B.V.
Establishment address:	Veenpluis 4-6 5684 PC Best The Netherlands
Establishment registration:	3003768277
Contact person:	Ilana Ben Moshe Regulatory Affairs Expert Phone: +972 525233496 Email: Ilana.Ben-Moshe@philips.com

II. Device information

Trade name:	IntelliSpace Portal Platform
Common name:	Image and Information Management Platform
Classification name:	Picture Archiving and Communications System (21 CFR 892.2050, Product Code LLZ)
Device classification:	Class II

III. Predicate device information

Trade name:	AW Server
Common name:	Picture Archiving and Communication System
Manufacturer:	GE Medical System, LLC
Classification name:	Picture Archiving and Communications System
Device classification:	Class II
510(k) clearance number:	K081985

Reference device no 1

Trade name:	Extended Brilliance Workplace a component of Brilliance iCT (Brilliance Volume)
Common name:	Workstation
Manufacturer:	Philips Medical Systems (Cleveland), Inc.
Classification name:	System, X-Ray, Tomography, Computed (21 CFR 992.1750, Product Code JAK)
Device classification:	Class II
510(k) clearance number:	K060937

Reference device no 2

Trade name:	MR Permeability Application
Common name:	Picture Archiving and Communication System
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification name:	Picture Archiving and Communication System (21 CFR 892.2050, Product Code LLZ)
Device classification:	Class II
510(k) clearance number:	K130278

Reference device no 3

Trade name:	ViewForum 2003
Common name:	Picture Archiving and Communication System
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification name:	Picture Archiving and Communication System (21 CFR 892.2050, Product Code LLZ)
Device classification:	Class II
510(k) clearance number:	K032096

Reference device no 4

Trade name:	IntelliSpace PACS 4.x
Common name:	Picture Archiving and Communication System
Manufacturer:	Philips Healthcare Informatics, Inc.
Classification name:	Picture Archiving and Communication System (21 CFR 892.2050, Product Code LLZ)
Device Classification	Class II
Clearance Number	K111804

Reference device no 5

Trade name:	EBW NM 2.0
Common name:	Picture Archiving and Communication System
Manufacturer:	Philips Medical Systems (Cleveland), Inc.
Classification name:	Picture Archiving and Communication System (21 CFR 892.2050, Product Code LLZ)
Device classification:	Class II
510(k) clearance number:	K111336

IV. Device description

Philips IntelliSpace Portal Platform is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images. This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications.

The IntelliSpace Portal Platform communicates with imaging systems of different modalities using the DICOM-3 standard.

V. Intended use

Philips IntelliSpace Portal Platform is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images. This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications.

IntelliSpace Portal Platform is intended to be used by trained professionals, including but not limited to physicians and medical technicians.

This medical device is not to be used for mammography.

The device is not intended for diagnosis of lossy compressed images.

VI. Technological characteristics

Philips believes that IntelliSpace Portal Platform product is substantially equivalent to the predicate GE AW Server legally marketed product with additional/enhanced functionality deriving from the reference devices:

- (K032096) ViewForum2003
- (K060937) Brilliance iCT (Brilliance Volume) EBW Workstation component
- (K130278) MR Permeability including details on IntelliSpace Portal component the next generation of the EBW product,
- (K111804) IntelliSpace PACS 4.4
- (K111336) EBW NM 2.0

Below is the comparison table to summarize the similarities and differences of the subject, predicate, and reference devices.

See Conclusion statement at the end of this section for substantial equivalency assessment of the differences indicated in the table.

#	Feature/ Capability	IntelliSpace Portal Platform Subject Device	AW Server Predicate Device (K081985)	Various (see details below) Reference Devices
System Configuration				
1	**Standard off the Shelf Hardware and Operating System (OS) requirements**	Yes	Yes	Not supported
2	**VMware Support**	Yes	Yes	Not supported
3	**Thin client-server technology**	Yes	Yes	Yes (K032096) ViewForum
4	**Dual monitor support**	1024x768 and up to 3MP	1024x768 and up to 3MP	Not supported
5	**Client multi-resolution display support**	1024x768 and up to 3MP	1024x768 and up to 3MP	Not supported
	System Applications and Functionality			
6	**Multiple concurrent user support**	Yes	Yes	Yes (K032096) ViewForum
7	**Patient directory / Report/ Film / Worklist application**	Yes	Not supported	Yes (K032096) ViewForum
8	**Presentation State Support**	Yes	Yes	Yes (K032096) ViewForum
9	**Pre-processing and background processing**	Yes	Yes	Yes (K032096) ViewForum
10	**CD/DVD burning**	Yes	Yes	Yes (K032096) ViewForum
11	**USB device support**	Yes	Not supported	Yes (K111804) IntelliSpace PACS 4.4

#	Feature/ Capability	IntelliSpace Portal Platform Subject Device	AW Server Predicate Device (K081985)	Various (see details below) Reference Devices
12	**Speech Recognition software (PowerScribe) for reporting**	Yes	Unknown	Yes (K032096) ViewForum
13	**Bookmarks: creating, saving, and loading**	Yes	Yes	Not supported
14	**Support of Lossy Compression for improved performance**	Yes	Yes	Yes (K032096) ViewForum
15	**Licensing**	Yes	Unknown	Yes (K130278) MR Permeability including IntelliSpace Portal
16	**Support of Data Pre-Fetch from remote devices**	Yes	Yes	Yes (K032096) ViewForum
17	**Management tool**	Yes	Yes	Yes (K032096) ViewForum
Review Modes and Image Manipulation				
18	**Support multi-modality data**	Yes	Yes	Yes (K032096) ViewForum
19	**2D slice view, Thin slab/ MPR view, 3D Volume Rendering/ MIP view /MiniP**	Yes	Unknown	Yes (K032096) ViewForum
20	**Fusion viewing**	Yes	Unknown	Yes (K032096) ViewForum (K111336) EBW NM 2.0
21	**MR Segmentation**	Yes	Unknown	Yes (K032096) ViewForum
22	**Cine viewing**	Yes	Yes	Yes (K032096) ViewForum
23	**Image Manipulation: scroll/pan/ zoom/rotate/ comparison/ merge**	Yes	Yes	Yes (K032096) ViewForum

#	Feature/ Capability	IntelliSpace Portal Platform Subject Device	AW Server Predicate Device (K081985)	Various (see details below) Reference Devices
24	**Send images and views to film application**	Yes	Yes	Yes (K032096) ViewForum
25	**Send images and views to a reporting application**	Yes	Yes	Yes (K032096) ViewForum
26	**Create image annotations**	Yes	Yes	Yes (K032096) ViewForum
27	**Measurement and graphics: ROI, angle, text**	Yes	Yes	Yes (K032096) ViewForum
Communication and Interoperability				
28	**Integration with institution's HIS, RIS, EMR**	Yes	Yes	Yes (K032096) ViewForum
29	**PACS integration**	Yes	Yes	Not supported
30	**Data Streaming tool integration**	Yes	Unknown	Not supported
31	**Multi-vendor Application plug-in**	Yes	Yes	Not supported
32	**Enterprise deployment (scalability feature)**	Yes	Yes	Not supported
33	**Multimodality Web Viewer (with any computer)**	Yes	Not supported	Not supported
34	**Multimodality Web Viewer - Mobile non-diagnostic viewing (Collaboration Viewer)**	Yes	Not supported	Not supported

Listed above technological differences are considered low risk, providing further support to clinicians in visualization or administrative functions. The majority of these functionalities are derived from reference devices and were verified and validated, and do not raise new questions on safety and/or effectiveness.

These features have not changed the intended use and operational principles of the device.

Therefore, the IntelliSpace Portal Platform is substantially equivalent to the currently marketed predicate device GE AW Server (K081985) in terms of technological characteristics.

Conclusion:

The IntelliSpace Portal Platform is substantially equivalent to the currently marketed predicate device, AW Server (K081985) in terms of indication for use, design features, fundamental scientific technology, and safety and/or effectiveness.

VII. Brief discussion of the nonclinical tests submitted, referenced or relied on

No performance standards for PACS systems or components have been issued under the authority of Section 514. Non-clinical performance testing has been performed on ISPP and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- 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

The ISPP system was tested in accordance with Philips verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

The test results in this 510(k) premarket notification demonstrate that ISPP:

- 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, ISPP is substantially equivalent to the currently marketed predicate device GE AW Server (K081985) in terms of safety and effectiveness.

VIII. Brief discussion of clinical tests submitted, referenced or relied on

The subject of this premarket submission, ISPP does not require clinical studies to support equivalence.

IX. The conclusions drawn from the nonclinical and clinical tests

Verification and Validation activities required to establish performance and functionality of IntelliSpace Portal Platform were performed. Testing involved system level tests, performance tests, and safety testing from Risk Analysis. Testing performed demonstrated the IntelliSpace Portal Platform meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The IntelliSpace Portal Platform is substantially equivalent to the predicate device AW Server (K081985) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.
Additionally, substantial equivalence was demonstrated with non-clinical performance testing, which complied with the requirements specified in the international and FDA-recognized consensus standards. The non-clinical performance tests provided in this 510(k) premarket notification demonstrate that the subject IntelliSpace Portal Platform is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.