Philips Healthcare Informatics, Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, Nw
BUFFALO, MN 55313

December 6, 2018

Re: K182926
Trade/Device Name: IntelliSpace Radiology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 27, 2018
Received: November 28, 2018

Dear Mark 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182926

Device Name
IntelliSpace Radiology

Indications for Use *(Describe)*
IntelliSpace Radiology Software (client) is a software package intended to be used by trained professionals, including but not limited to Radiologists, physicians, administrators and medical technicians.

The software is used with general purpose computing hardware for the presentation, processing, measurement and distribution of images and associated data throughout a clinical environment.

IntelliSpace Radiology contains an Advanced Mammography module for functionality specific to Mammography. Lossy compressed mammographic images and digitized film/screen images must not be reviewed for primary image interpretations.

Mammography images may only be interpreted using display monitors approved for digital 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.

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5 510(K) SUMMARY

510(k) Summary

IntelliSpace Radiology

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92.

Date Prepared: September 5, 2018

I. Submitter's name and address

Manufacturer: Philips Healthcare Informatics, Inc.
4430 Rosewood Drive, Suite 200
Pleasanton, CA 94588
USA
Establishment Registration Number: 2954704

Contact Person: Elfriede Pagan
Sr. Manager, Regulatory Affairs
Phone: (321) 339-9144
E-mail: phiiregulatory@philips.com

II. Device information

Subject Device:

Device Name:	IntelliSpace Radiology
Common/Usual Name:	Radiology Image and Information Management System
Classification:	
Classification name:	Picture Archiving and Communications System
Device class:	Class II
Classification regulation:	21 CFR 892.2050
Classification panel:	Radiology
Product Code:	LLZ

III. Predicate device information

Predicate Device:

Trade name:	IntelliSpace PACS 4.x
Manufacturer:	Philips Healthcare Informatics, Inc.
510(k) clearance:	K111804
Classification name:	Picture Archiving and Communications System
Device class:	Class II
Classification regulation:	21 CFR 892.2050
Classification panel:	Radiology
Product code:	LLZ

IV. Device Description

The subject device IntelliSpace Radiology product described in this section is a modification of the previously cleared IntelliSpace PACS 4.x software device (K111804). Changes made or being implemented are described in Section 12 'Substantial Equivalence Discussion'.

IntelliSpace Radiology is a software package intended to be used by trained professionals, including but not limited to physicians, administrators and medical technicians.

The software is used with general purpose computing hardware for the presentation, processing, measurement and distribution of images and associated data throughout a clinical environment.

IntelliSpace Radiology software supports receiving, sending, printing, and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, CR, DX, DR, RF, RT, MG, SC, VL, and OP as well as hospital/radiology information systems.

IntelliSpace Radiology contains an Advanced Mammography module for functionality specific to Mammography. Lossy compressed mammographic images and digitized film/screen images must not be reviewed for primary image interpretations.

V. Indications for Use

IntelliSpace Radiology Software (client) is a software package intended to be used by trained professionals, including but not limited to Radiologists, physicians, administrators and medical technicians.

The software is used with general purpose computing hardware for the presentation, processing, measurement and distribution of images and associated data throughout a clinical environment.

IntelliSpace Radiology contains an Advanced Mammography module for functionality specific to Mammography. Lossy compressed mammographic images and digitized film/screen images must not be reviewed for primary image interpretations.

Mammography images may only be interpreted using display monitors approved for digital mammography.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device IntelliSpace Radiology (ISR) product described in this section is a modification of the previously cleared IntelliSpace PACS 4.x software device (K111804). The software is used with general purpose computing hardware for the presentation, processing, measurement and distribution of images and associated data throughout a clinical environment by healthcare professionals.

IntelliSpace Radiology product uses the standard principles of operation typically seen in PACS systems such as database and image management systems, image processing tools, and standard measurement tools. Both the subject device and the predicate device provide Diagnostic Review Solution for radiology and other areas where images are utilized, such as Visible Light. ISR is utilizing client–server technology, communication and interoperability with hospital systems, such as radiology workflow providers and image archives.

A comparison matrix below (please see Table 5-1 below) provides a comparison which outlines a high-level overview of the differences and similarities between IntelliSpace Radiology and the predicate device, IntelliSpace PACS 4.x (K111804).

Table 5-1 Technological characteristics comparison

#	Specification / Feature	IntelliSpace Radiology (subject device)	Predicate IntelliSpace PACS 4.x (K111804)
1.	**Software Image and Information management system**	Yes	Yes
2.	**Hardware Platform requirements**	Yes	Yes
System Configuration			
3.	**Windows Operating System**	Yes	Yes
4.	**TCP-IP Network Protocol**	Yes	Yes
5.	**Supports High Resolution Diagnostic Monitors**	Yes	Yes
6.	**Storage capabilities**	Not supported	Yes
7.	**Multiple monitor support**	Yes	Yes
Communication and Interoperability with other image management systems			
8.	**Supports DICOM studies received from different modalities types**	Yes - CT, MR, NM, US, XA, PET, CR, DX, DR, RF, RT, MG, SC, VL, and OP	Yes- CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL
9.	**Support for IHE Profiles for Key Image Notes (KIN) and Digital Breast Tomosynthesis (DBT)**	Yes	No
Operating Platform requirements			
10.	**Client-server technology**	Yes	Yes
11.	**Thin client installer**	Yes	Yes
12.	**Multiple concurrent user support**	Yes	Yes
Interfaces with other Image management systems			

#	Specification / Feature	IntelliSpace Radiology (subject device)	Predicate IntelliSpace PACS 4.x (K111804)
13.	**Supported Data and Multi Modalities**	Supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, CR, DX, DR, RF, RT, MG, SC, VL, and OP as well as hospital/ Radiology information systems.	Supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL as well as hospital/ Radiology information systems.
14.	**Federation**	Yes	Yes
15.	**Vendor Neutral Archive for Client**	Yes	Yes
Patient-Exam Worklist Browser			
16.	**Patient Exam Query Tool**	Yes	Yes
17.	**Patient Exam Worklist Filters**	Yes	Yes
Image Display/Formatting/Navigation			
18.	**Multiple Monitor layout option**	Yes	Yes
19.	**Scales image to window**	Yes	Yes
20.	**Next/Previous Image/ Series/ Page Options**	Yes	Yes
21.	**Cine Toolset**	Yes	Yes
22.	**Image/Series Linking**	Yes	Yes
23.	**Image Rotate/Flip**	Yes	Yes
24.	**Image Zoom/Pan**	Yes	Yes
25.	**Scout lines Tool**	Yes	Yes
26.	**Image Stacking**	Yes	Yes
27.	**Hanging Protocols**	Yes	Yes
28.	**Grayscale Softcopy Presentation State (GSPS)**	Yes	Yes
29.	**Tomosynthesis Slice Indicator**	Yes	No
30.	**Bidirectional Tomo Localizer**	Yes	No
31.	**Tomo Slab View**	Yes	No
32.	**Tomo Localizer Mode**	Yes	No
Measurement and Annotations			
33.	**Measurement Tools**	Yes	Yes
34.	Linear Measurements (Ruler)	Yes	Yes
35.	Angle	Yes	Yes
36.	Cobb Measurement	Yes	Yes
37.	ROI Circle	Yes	Yes
38.	ROI Freehand	Yes	Yes
39.	ROI Ellipse	Yes	Yes

#	Specification / Feature	IntelliSpace Radiology (subject device)	Predicate IntelliSpace PACS 4.x (K111804)
40.	Point Value	Yes	Yes
41.	Calibrating Images	Yes	Yes
42.	Angle Line Ratio	Yes	No
43.	Ultrasound Measurements	Yes	Yes
44.	**Annotation Tools**	Yes	Yes
Results			
45.	**View/Print Diagnostic Reports from RIS**	Yes	Yes
Printing/Export/Save Images…			
46.	**Printing images to Paper**	Yes	Yes
47.	**Printing images to Film**	Yes	Yes
48.	**Save images as BMP, JPEG, TIF files**	Yes	Yes
49.	**Export of Patient-Exams**	Yes	Yes
General Usage			
50.	**Designed for diagnostic review of images inside and outside of Radiology**	Yes	Yes
Clinical Tools			
51.	**Remote Reading Tools / Teleradiology**	Yes	Yes
52.	**Image Filters**	Yes	Yes
53.	**Variable Slice Thickness for CT (Slab Reading)**	Yes	Yes
54.	**Exam Notes**	Yes	Yes
55.	**Key Image Series**	Yes	Yes
56.	**Patient Merging**	Yes	Yes
57.	**Standard Mammography**	Yes	Yes
58.	**Advanced Mammography Module**	Yes	No
Management Tools			
59.	**Patient Management**	Yes	Yes
60.	**Exam Management**	Yes	Yes
61.	**Exception Study**	Yes	Yes
62.	**User Security Access Management**	Yes	Yes
63.	**Dictionary Management**	Yes	Yes
64.	**Auditing Tools**	Yes	Yes
65.	**Billing**	Yes	Yes
66.	**Easy Client Installer**	Yes	Yes
67.	**Data Migration**	Yes	Yes
68.	**Workflow Layer**	Yes	Yes
69.	**System Monitoring**	Yes	Yes
Third Party Application Support			
70.	**PowerScribe**	Yes	Yes
71.	**Cardiology Enterprise Viewer**	Yes	Yes
72.	**Application Programming Interface**	Yes	Yes
73.	**Universal Data Manager**	Yes	No
74.	**IntelliSpace PACS Anywhere**	Yes	No
75.	**IntelliSpace Clinical Applications**	Yes	Yes

The subject device, IntelliSpace Radiology, has implemented features designated to bring the product up to date with current technologies and customer requests. Presented technological differences are considered low risk, providing further support to clinicians in visualization. These functionalities 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, IntelliSpace Radiology is substantially equivalent to the currently marketed predicate device IntelliSpace PACS 4.x (K111804) in terms of technological characteristics.

VII. Performance Data

Section 16 'Software' provides a summary of the technical documentation, which includes nonclinical verification and validation tests. These tests are performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results, and according to the following International and FDA-recognized consensus standards and FDA guidance document.
The following performance data was provided in support of the substantial equivalence determination.

Summary of Non-clinical testing
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 IntelliSpace Radiology product 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
- IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices
- 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

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could resultlead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to a minor injury to the patient or operator.

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

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

- 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.

Additionally, the risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable.
Therefore, IntelliSpace Radiology is substantially equivalent to the currently marketed predicate device IntelliSpace PACS 4.x (K111804) in terms of safety and effectiveness.

Summary of Clinical Testing
The subject of this premarket submission, IntelliSpace Radiology did not require clinical studies to support equivalence.

VIII. Substantial Equivalence Conclusion

IntelliSpace Radiology is substantially equivalent to the currently marketed predicate device IntelliSpace PACS 4.x (K111804) in terms of indications for use, design features, fundamental scientific technology, and safety and/or effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance testing. Verification and Validation (V&V) activities were performed for proposed IntelliSpace Radiology system and demonstrated that the predetermined acceptance criteria were successfully met. The non-clinical performance tests provided in this 510(k) premarket notification demonstrated that the subject device IntelliSpace Radiology is as safe and effective as its predicate device IntelliSpace PACS 4.x (K111804) without raising any new safety and/or effectiveness concerns.