



Food and Drug Administration
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February 19, 2016

Philips Medical Systems Nederland BV
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K160315

Trade/Device Name: I4 (integrated Intelligent Imaging Informatics) System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, JAK
Dated: February 3, 2016
Received: February 5, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)

K160315

Device Name

I4 (Integrated Intelligent Imaging Informatics) system

Indications for Use (Describe)

I4 (Integrated Intelligent Imaging Informatics) is an image management system intended to be used by trained professionals, including but not limited to radiologists.

I4 (Integrated Intelligent Imaging Informatics) system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for 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.

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510(k) Summary

I4 (Integrated Intelligent Imaging Informatics)

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

Date Prepared: December 15, 2015

I. Submitter's name and address

Manufacturer: Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

Contact Person: Ilana Ben Moshe
Regulatory Affairs Expert
Phone: +972 525233496
E-mail: Ilana.Ben-Moshe@philips.com

II. Device information

Subject Device:

Device Name:	I4 (Integrated Intelligent Imaging Informatics) system
Common/Usual Name:	Imaging Informatics System
Classification:	
Classification name:	Picture Archiving and Communications System
Device class:	Class II
Classification regulation:	21 CFR 892.2050
Classification panel:	Radiology
Primary Product Code:	LLZ
Secondary Product Code:	JAK

III. Predicate device information**Primary 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

Reference Predicate Devices:

Trade name: ViewForum 2003
 Manufacturer: Philips Medical Systems North America Company
 510(k) clearance: K032096
 Classification name: System, Image Processing
 Device class: Class II
 Classification regulation: 21 CFR 892.2050
 Classification panel: Radiology
 Product code: LLZ

Trade name: Brilliance iCT (Brilliance Volume)
 Manufacturer: Philips Medical Systems(Cleveland), Inc.
 510(k) clearance: K060937
 Classification name: System, X-Ray, Tomography, Computed
 Device class: Class II
 Classification regulation: 21 CFR 892.1750
 Classification panel: Radiology
 Product code: JAK

Reference Device:

Trade name: VesselNavigator
 Manufacturer: Philips Medical Systems Nederland B.V.
 510(k) clearance: K151598
 Classification name: Image-intensified fluoroscopic x-ray system
 Device class: Class II
 Classification regulation: 21 CFR 892.1650
 Classification panel: Radiology
 Product code: OWB, LLZ

IV. Device Description

I4 (Integrated Intelligent Imaging Informatics) is an image management system intended to be used by trained professionals, including but not limited to radiologists.

I4 (Integrated Intelligent Imaging Informatics) system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for mammography.

I4 (Integrated Intelligent Imaging Informatics) is a medical software system offering a primary interpretation solution for visualization and evaluation a variety of medical images deriving from various imaging modalities as well as non-imaging information. I4 interconnects with clinical imaging and non-imaging data sources to present in addition to images non-imaging data in patient context.

V. Indications for Use

I4 (Integrated Intelligent Imaging Informatics) is an image management system intended to be used by trained professionals, including but not limited to radiologists.

I4 (Integrated Intelligent Imaging Informatics) system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, manipulation and quantification of images, communication and storage.

This device is not to be used for mammography.

Indications for Use Discussion

The proposed device I4 (Integrated Intelligent Imaging Informatics) system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment, identical to the primary predicate device, IntelliSpace PACS 4.x (K111804).

I4 (Integrated Intelligent Imaging Informatics) software is designed to perform digital image processing, measurement, manipulation and quantification of images, communication and storage with indications for use similar to the primary predicate device, IntelliSpace PACS 4.x (K111804).

The Indications for Use statement for I4 (Integrated Intelligent Imaging Informatics) is similar, but not identical compared to the primary predicate device, IntelliSpace PACS 4.x (K111804), and the two devices have the same intended use.

- I4 (Integrated Intelligent Imaging Informatics) software provides digital image processing function of performing image manipulation (e.g 3D rendering modes and 3d visualization) with advanced visualization and evaluation capabilities of cleared to market reference predicate devices ViewForum 2003(K032096), Brilliance iCT (Brilliance Volume)(K060937).I4 system indications for use are a combination of primary predicate device and reference predicate devices, and falls within the intended use of the primary predicate device.

This difference does not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the primary predicate IntelliSpace PACS 4.x (K111804). Both the proposed and the primary predicate device have the same intended use, a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment.
- I4 (Integrated Intelligent Imaging Informatics) system is not to be used for mammography. This is a reduction of the IntelliSpace PACS 4.x (K111804) Indications for Use scope. This limitation is clearly indicated in the labelling and does not raise new questions on safety and/or effectiveness

Listed above differences do not alter the intended use nor do they affect the safety and effectiveness of the device relative to the primary predicate device, IntelliSpace PACS 4.x (K111804).

Based on the above, the proposed I4 (Integrated Intelligent Imaging Informatics) is considered substantially equivalent to the currently marketed and primary predicate device IntelliSpace PACS 4.x (K111804), in terms of Indications for use.

VI. Comparison of Technological Characteristics with the Predicate Device

I4 (Integrated Intelligent Imaging Informatics) system is an evolution of the primary predicate device IntelliSpace PACS 4.x (K111804) with additional/enhanced functionality deriving from the reference predicate devices ViewForum2003 (K032096), Brilliance iCT (Brilliance Volume) (K060937), and reference device VesselNavigator (K151598).

I4 (Integrated Intelligent Imaging Informatics) is a software package used with general purpose computing hardware.

I4 (Integrated Intelligent Imaging Informatics) system uses the standard principles of operation typically seen in PACS systems such as database and image management systems, image processing tools, standard measurement tools.

Both the proposed device and the primary predicate device provide Diagnostic Review Solution for radiology, utilizing client –server technology, storage capabilities, communication and interoperability with hospital systems, such as radiology workflow providers and image archive.

A comparison matrix below (please see Table 0-1 below) provides a comparison which outlines a high level overview of the differences and similarities between I4 (Integrated Intelligent

Imaging Informatics) system and the primary predicate device, IntelliSpace PACS 4.x (K111804), reference predicate devices, ViewForum2003 (K032096), Brilliance iCT (Brilliance Volume) (K060937), and reference device VesselNavigator (K151598).

Table 5-1 Technological characteristics comparison

#	Specification / Feature	Proposed Device:	Primary Predicate Device	Reference predicate Devices:
		I4 (Integrated Intelligent Imaging Informatics) system	IntelliSpace PACS 4.x (K111804)	Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
1.	Software Image management system	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
2.	Hardware Platform requirements	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
System Configuration				
3.	Windows Operating System	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
4.	TCP-IP Network Protocol	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate

#	Specification / Feature	Proposed Device:	Primary Predicate Device	Reference predicate Devices:
		I4 (Integrated Intelligent Imaging Informatics) system	IntelliSpace PACS 4.x (K111804)	Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
5.	Supports High Resolution Diagnostic Monitors	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
6.	Storage capabilities	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
7.	Multiple monitor support	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
Communication and Interoperability with other image management systems				
8.	Supports DICOM studies received from different modalities types	Yes - CT, MR, US, XA, DX, CR, RF, PT and SC as well as hospital/radiology information systems	Yes- CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL	Yes - CT, MR
9.	Mammography	No	Yes	Not relevant for this subject comparison as I4 system do not support Mammography

#	Specification / Feature	Proposed Device: I4 (Integrated Intelligent Imaging Informatics) system	Primary Predicate Device IntelliSpace PACS 4.x (K111804)	Reference predicate Devices: Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
10.	Accepts patient and exam updates via HL7	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
Operating Platform requirements				
11.	Client-server technology	Yes	Yes	No - SW designed for use on workstations only.
12.	Thin client installer	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
13.	Multiple concurrent user support	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
Management tools				
14.	Auditing Tool	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate

#	Specification / Feature	Proposed Device:	Primary Predicate Device	Reference predicate Devices:
		I4 (Integrated Intelligent Imaging Informatics) system	IntelliSpace PACS 4.x (K111804)	Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
15.	Client installer	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
16.	System management	Yes	Yes	Not relevant for this subject comparison as the proposed device utilizes similar technology as the primary predicate
Viewing and Image Processing				
17.	Supported Data and Multi Modalities	Supports receiving, sending, storing and displaying studies received from the following modalities via DICOM: CT, MR, US, XA, DX, CR, RF, PT and SC 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, PT, DX, DR, RF, RT, MG, SC, VL, as well as hospital/ Radiology information systems.	CT, MR
18.	2D basic viewing: Multiple monitor layout options , Scales image to window, Cine	Yes	Yes	Yes

#	Specification / Feature	Proposed Device:	Primary Predicate Device	Reference predicate Devices:
		I4 (Integrated Intelligent Imaging Informatics) system	IntelliSpace PACS 4.x (K111804)	Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
19.	2D Advanced viewing: Compare series side-by-side, Multi-Dimensional viewing	Yes	No	Yes- ViewForum2003 (K032096)
20.	3D volumetric viewing : Volumetric image	Yes	No	Yes -Brilliance iCT (Brilliance Volume) (K060937)
21.	Multi Planar Reconstruction (MPR)	Yes	No	Yes -Brilliance iCT (Brilliance Volume) (K060937)
22.	3D Rendering modes (MIP, MinIP, VIP Surface MIP, Average(AIP), Volume rendering)	Yes	No	Yes -Brilliance iCT (Brilliance Volume) (K060937)
23.	Comparison and Synchronization between volumetric series	Yes	No	Yes- ViewForum2003 (K032096)
24.	Image manipulation: Slab thickness and orientation (for MPR images), windowing, zoom level, pan	Yes	No	Yes -Brilliance iCT (Brilliance Volume) (K060937)
25.	Measurements and Annotations tools (for 2D and 3D viewing): Straight Line, Curved Line, ROI, Angle, text, measurement comparison	Yes- Measurements and Annotations tools for 2D and 3D viewing modes	Yes- Measurements and Annotations tools for 2D viewing mode	Yes- Brilliance iCT (Brilliance Volume) (K060937)
26.	Segmentation tools: Bone/Skull removal	Yes	No	Yes- Advance Vessel Analysis (AVA) from Brilliance iCT (Brilliance Volume), (K060937)

#	Specification / Feature	Proposed Device:	Primary Predicate Device	Reference predicate Devices:
		I4 (Integrated Intelligent Imaging Informatics) system	IntelliSpace PACS 4.x (K111804)	Brilliance iCT (Brilliance Volume) (K060937) ViewForum2003 (K032096) Reference device: VesselNavigator (K151598)
27.	Advanced vessel analysis visualization and evaluation mode (Vascular Inspection Mode)	Yes	No	Yes – ViewForum 2003(K032096), Brilliance iCT (Brilliance Volume) (K060937), and VesselNavigator (K151598). I4 incorporate functionalities from all listed reference predicate devices.
28.	Incorporation of non-imaging data in patient context (Mission Briefing)	Yes	No	No

The subject device, I4 (Integrated Intelligent Imaging Informatics) system, 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 are derived from reference predicate devices and reference device, 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 I4 (Integrated Intelligent Imaging Informatics) system is substantially equivalent to the currently marketed primary predicate device IntelliSpace PACS 4.x (K111804) in terms of technological characteristics.

VII. Performance Data

The following performance data were 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 I4 (Integrated Intelligent Imaging Informatics) system 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

I4 (Integrated Intelligent Imaging Informatics) 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 I4 (Integrated Intelligent Imaging Informatics) system:

- 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, I4 (Integrated Intelligent Imaging Informatics) system is substantially equivalent to the currently marketed primary predicate device IntelliSpace PACS 4.x (K111804) in terms of safety and effectiveness.

Summary of Clinical Testing

The subject of this premarket submission, I4 (Integrated Intelligent Imaging Informatics) system did not require clinical studies to support equivalence.

VIII. Substantial Equivalence Conclusion

The I4 (Integrated Intelligent Imaging Informatics) system is substantially equivalent to the currently marketed primary 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. The non-clinical performance tests provided in this 510(k) premarket notification demonstrated that the proposed I4 (Integrated Intelligent Imaging Informatics) system is as safe and effective as its primary predicate device IntelliSpace PACS 4.x (K111804) without raising any new safety and/or effectiveness concerns.