



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

November 18, 2015

Re: K153022

Trade/Device Name: Philips Intellispace Cardiovascular  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: November 5, 2015  
Received: November 6, 2015

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

## Indications for Use

510(k) Number (if known)

K153022

Device Name

Philips IntelliSpace Cardiovascular

Indications for Use (Describe)

Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.

Philips IntelliSpace Cardiovascular offers support for third party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification and reporting. It allows multiple users fast access to, and exchange of specific and/or multiple cardiology exams.

Philips IntelliSpace Cardiovascular software runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using standard protocols. Philips IntelliSpace Cardiovascular will also be made available for use on specified Cardiovascular Monitoring Systems, which use suitable hardware components.

The modular design allows configurability to tailor the image import, archive and communications solution to one's particular budgetary and performance needs. The number of modalities and reporting and/or viewing sites can be configured per system.

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.

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**510(k) Summary****IntelliSpace Cardiovascular**

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

Date Prepared: September 30, 2015

**I. Submitter's name and address**

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

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 Quality and Regulatory Manager  
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 E-mail: [dave.bierhuizen@philips.com](mailto:dave.bierhuizen@philips.com)

**II. Device information**

Device Name: IntelliSpace Cardiovascular  
 Common Name: Cardiovascular 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: Philips Xcelera  
 Manufacturer: Philips Medical Systems Nederland B.V.  
 510(k) clearance: K061995  
 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**

IntelliSpace Cardiovascular is a comprehensive cardiac image and information management solution designed to provide clinicians with convenient access to the detailed records of all cardiac patients across their complete cardiovascular care continuum. The application also provides hospital administrators and department managers with detailed operational information, as well as productivity and outcomes reporting. Key components include a wide range of detailed clinical modules that capture data during diagnostic/therapeutic procedures and patient follow-up encounters. Interfaces to other systems and devices within the cardiology departments as well as across the enterprise system, such as HIS/EMR, are available.

The solution supports a remote deployment model.

## **V. Intended use/ Indications for Use**

### **Intended Use**

Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images.

### **Indication for Use**

Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images, waveforms and data related to cardiology.

Philips IntelliSpace Cardiovascular offers support for third party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification and reporting. It allows multiple users fast access to, and exchange of specific and/or multiple cardiology exams.

Philips IntelliSpace Cardiovascular software runs on standard information technology hardware and software, utilizing the standard information technology operating systems and user interface. Communication and data exchange are done using standard protocols. Philips IntelliSpace Cardiovascular will also be made available for use on specified Cardiovascular Monitoring Systems, which use suitable hardware components.

The modular design allows configurability to tailor the image import, archive and communications solution to one's particular budgetary and performance needs. The number of modalities and reporting and/or viewing sites can be configured per system.

## **VI. Comparison of Technological Characteristics with the Predicate Device**

Philips IntelliSpace Cardiovascular (ISCV) software is an integrated multimodality image and information system, which employs and further builds on the same fundamental scientific technology as the Philips Xcelera software.

IntelliSpace Cardiovascular software runs on standard information technology hardware and software.

IntelliSpace Cardiovascular does not interact with the patient, and does not apply any radiation or contrast agent to the patient.

A comparison matrix (please see Table 5-1 below) shows the similarities and differences. The ISCV software with the listed enhancements is comparable to the previously cleared Xcelera product as the changes do not impact the Intended Use or patient population. Enhancements relate to upgrades in current standard IT application and technology environment or clinical practices to improve customer workflows. All changes are implemented and tested utilizing released design and change control processes. No new issues of safety or effectiveness are raised as compared to the predicate device.

Table 5-1 Comparison Table of the modified ISCV to the predicate Xcelera product.

#	Specification / Feature	IntelliSpace Cardiovascular (Subject device)	Xcelera (Predicate device - K061995)
	<b>Intended Use / Target population</b>		
1.	<b>Intended Use</b>	Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images.	Philips Xcelera software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images.
2.	<b>Target population</b>	Patients undergoing radiology procedures and the users of the equipment.	Patients undergoing radiology procedures and the users of the equipment.

#	Specification / Feature	IntelliSpace Cardiovascular (Subject device)	Xcelera (Predicate device - K061995)
	<b>Technology</b>		
3.	<b>Hardware Platform requirements</b>	Standard IT hardware	Standard IT hardware
4.	<b>Operating Platform requirements</b>	Current industry standard versions of server and desktop operating systems.	Industry standard versions of server and desktop operating systems.
5.	<b>Browser support</b>	Thin clients are supported on HTML5 capable browsers.	Not supported
6.	<b>Virtualization</b>	Server virtualization enabled with VMWare	Not supported
7.	<b>Imaging and Other Communications Protocols</b>	TCP/IP, DICOM, DSR, HL7, NFS, FTP	TCP/IP, DICOM, DSR, HL7, NFS, FTP
8.	<b>Support for launching 3<sup>rd</sup> party medical devices</b>	Plug-in support for: ultrasound, cardiovascular X-ray, nuclear medicine, computed tomography, magnetic resonance, and electrophysiology studies.  URL launch of 3 <sup>rd</sup> party medical devices (that allow URL launch)	Plug-in support for: ultrasound, cardiovascular X-ray, nuclear medicine, computed tomography, magnetic resonance, and electrophysiology studies.
9.	<b>EMR/HIS Interface</b>	A mechanism to launch from the EMR system directly into ISCV, and into the EMR.	Not supported
10.	<b>Integration with Philips information management systems</b>	<ul style="list-style-type: none"> <li>TSM (Table Side Module)</li> <li>Xper IM</li> <li>Philips CVIS</li> </ul>	<ul style="list-style-type: none"> <li>TSM (Table Side Module)</li> <li>Xper IM</li> </ul>
11.	<b>System entry screen</b>	Browser-based workspace with applets, system extensions and workflow modules. Provides two layers: user-centric, for search and configurable worklist functionality; patient-centric: for detailed cardiovascular history.	Main window including configurable worklist.
	<b>Archiving</b>		
12.	<b>Automatic Study placement and folder creation</b>	Yes	Yes
13.	<b>Study and Patient Management, incl. delete images from study, study split, merge, and enterprise master patient index</b>	Yes	Not supported
14.	<b>Study Type</b>	Ultrasound, Nuclear medicine, X-ray (cath and invasive vascular), all other modality types related to cardiology.	Ultrasound, Nuclear medicine, X-ray (cath)
15.	<b>DICOM SR Mapping Tooling</b>	Yes	Not supported
16.	<b>Customized measurements and calculations tool</b>	Yes	Yes
17.	<b>PDF Import</b>	Import reports that are in PDF format from external sources.	Not supported
18.	<b>Data Mining</b>	Supported	Supported
	<b>Viewing</b>		
19.	<b>Supported Data and Modalities</b>	<ul style="list-style-type: none"> <li>All DICOM formats as stated in the DICOM, including but not limited to: Ultrasound, Cath, CT and MR.</li> <li>Philips' proprietary ultrasound image format (DSR-TIFF).</li> </ul>	<ul style="list-style-type: none"> <li>All DICOM formats as stated in the DICOM, including but not limited to: Ultrasound, Cath, CT and MR.</li> <li>Philips' proprietary ultrasound image format (DSR-TIFF).</li> </ul>
20.	<b>Cath Viewer</b>	Yes	Yes
21.	<b>Echo Viewer</b>	Yes	Yes
22.	<b>Remote Viewing (thin client)</b>	Zero-install (thin) client, browser based technology (HTML5) to perform review-only of series, runs, loops and images.	Not supported
	<b>Quantification and Reporting</b>		
23.	<b>Cath Viewer Measurements</b>	Simple distance measurements (non-persistent)	Simple distance measurements (non-persistent)

#	Specification / Feature	IntelliSpace Cardiovascular (Subject device)	Xcelera (Predicate device - K061995)
24.	Cath Quantitative Analysis	Yes	Yes
25.	Echo Measurements and Calculations	<ul style="list-style-type: none"> <li>• 2D</li> <li>• Doppler</li> <li>• MMode</li> <li>• Trending graph of measurements and z-scores</li> <li>• Z-scores: Michigan data</li> </ul>	<ul style="list-style-type: none"> <li>• 2D</li> <li>• Doppler</li> <li>• MMode</li> <li>• Trending graph of measurements and z-scores</li> <li>• Z-scores: Michigan data</li> </ul>
26.		<ul style="list-style-type: none"> <li>• Z-scores: extensions of z-scores data (Boston)</li> </ul>	Not supported
27.		<ul style="list-style-type: none"> <li>• Blood Pressure import from DICOM SR files from vendors (Philips, GE, Siemens, Toshiba)</li> </ul>	Not supported
28.	Diagnostic Guidance	Consistency check mechanism that will allow clinicians to predefine a set of rules.	Not supported
29.	Remote reporting (tele-cardiology)	View the study from a remote location and perform reporting tasks on the study.	Not supported
30.	Remote Echo Reporting (thin client)	Thin client, browser based technology (HTML5) to perform diagnostic review and 2D measurements on echo images. Supported on standard PC hardware; not supported on mobile devices.	Not supported
	Other		
31.	System access	Define user rights based on institute level.	Global user rights
32.	Single access to configuration	Configure ISCV in a singular place	Not supported

## 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. IntelliSpace Cardiovascular was tested in accordance with Philips verification and validation processes. Quality Assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validations

### **Summary of Clinical Testing**

The subject of this premarket submission, IntelliSpace Cardiovascular software did not require clinical studies to support equivalence.

### **Conclusions drawn from the Non-clinical and Clinical testing**

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

## VIII. Conclusion

The IntelliSpace Cardiovascular is substantially equivalent to the predicate device Xcelera (K061995) in terms of design features, fundamental scientific technology, intended 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 Cardiovascular is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.