Philips Medical Systems Nederland B.V.
Roopak Krishna
Regulatory Affairs Manager
Veenpluis 6
5684 PC
Best
Netherlands

October 2, 2025

Re: K251215
Trade/Device Name: Philips IntelliSpace Cardiovascular
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 5, 2025
Received: September 8, 2025

Dear Roopak Krishna:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251215

Please provide the device trade name(s).

Philips IntelliSpace Cardiovascular

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

Philips IntelliSpace Cardiovascular

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

Company's Name and Address	Philips Medical Systems Nederland B.V. Veenpluis 4 5684 PC Best The Netherlands
Contact Person	Roopak Krishna Regulatory Affairs Manager roopak.mt@philips.com +31-687-963-967
Date	April 18, 2025
Device Tradename	Philips IntelliSpace Cardiovascular
Classification Name	Medical image management and processing system
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Predicate Device	Philips IntelliSpace Cardiovascular (K153022)

1. Device Description and Technological Characteristics

Philips 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 solution 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.

2. Indications 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.

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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.

3. Comparison of Technological Characteristics with the Predicate Device

IntelliSpace Cardiovascular 9.1 employs and further builds on the same fundamental scientific technology of IntelliSpace Cardiovascular 2.0 (predicate K153022) with enhanced or expanded functionalities in virtualization, imaging and communications protocols, echo measurements and calculations as well as tooling for user-configuration. Table 1 below summarizes the similarities and differences between the subject device and the predicate. None of these differences raises new safety and effectiveness question.

Table 1: Substantial Equivalence

Differences between the predicate and subject device in the table below:

Comparison feature	Philips IntelliSpace Cardiovascular 9.1 (Subject device – K251215)	Philips IntelliSpace Cardiovascular 2.0 (Predicate device – K153022)
Intended Use / Target population		
Intended Use	Same as predicate device.	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.
Target population	Same as predicate device.	Patients undergoing radiology procedures and the users of the equipment.
Technology		
Hardware Platform requirements	Same as predicate device.	Standard IT hardware
Operating Platform requirements	Same as predicate device.	Industry standard versions of server and desktop operating systems.
Browser support	Same as predicate device.	Thin clients are supported on HTML5 capable browsers.
Virtualization	Same as predicate device.	Server virtualization enabled with VMWare
	Amazon Elastic Compute Cloud (EC2) for cloud server virtualization.	Deployment model not supported in predicate device.
Imaging and Other Communications Protocols	TCP/IP, DSR, HL7, NFS	TCP/IP, DSR, HL7, NFS, FTP
	DICOM support (Classic DICOM) DICOMWeb: QIDO-RS, WADO-RS and STOW-RS	DICOM support (Classic DICOM)
Support for launching third-party medical devices	Same as predicate device.	Plug-in support for: ultrasound, cardiovascular X-ray, nuclear medicine, computed tomography, magnetic resonance, and electrophysiology studies. URL launch of 3rd party medical devices

		(that allow URL launch)
EMR/HIS Interface	Same as predicate device.	A mechanism to launch from the EMR system directly into IntelliSpace Cardiovascular, and into the EMR.
Integration with Philips information management systems	Same as predicate device.	• TSM (Table Side Module) • Xper IM • Philips CVIS
System entry screen	Same as predicate device.	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.
Archiving		
Automatic Study placement and folder creation	Same as predicate device.	Supported in predicate device.
Study management	Same as predicate device.	Supported in predicate device.
Study type	Same as predicate device.	Ultrasound, Nuclear medicine, X-ray (cath and invasive vascular), all other modality types related to cardiology.
Customized measurements and calculations tool	Same as predicate device.	Supported in predicate device.
PDF Import	Same as predicate device.	Import reports that are in PDF format from external sources.
Database views	Same as predicate device.	Supported in predicate device.
Viewing		
Supported Data and Modalities	Same as predicate device.	• All DICOM formats as stated in the DICOM, including but not limited to: Ultrasound, Cath, CT and MR. • Philips' proprietary ultrasound image format (DSR-TIFF).
Cath Viewer	Same as predicate device.	Supported in predicate device.
Echo Viewer incl. diagnostic quality (thin client)	Same as predicate device.	View ultrasound images with diagnostic quality.
Remote Viewing (thin client)	Same as predicate device.	Zero-install (thin) client, browser-based technology (HTML5) to perform review-only of series, runs, loops and images.
Quantification and Reporting		
Cath Viewer Measurements	Same as predicate device.	Simple distance measurements (non-persistent)
Cath Quantitative Analysis	Same as predicate device.	Analysis on cardiac catheterization images
Echo Measurements and Calculations	Same as predicate device.	• 2D • Doppler • MMode • Trending graph of measurements and Z-scores

		• Z-scores: Michigan data • Z-scores: extensions of z-scores data (Boston) • Blood Pressure import from DICOM SR files from vendors (Philips, GE, Siemens, Toshiba)
	• Z-scores: Pediatric Heart Network (PHN 2017) • Z-scores: Boston 2017 • Z-scores: Krishnan et al	Not supported on predicate device.
Diagnostic Guidance	Same as predicate device.	Consistency check mechanism that will allow clinicians to predefine a set of rules.
Remote reporting (tele-cardiology)	Same as predicate device.	View the study from a remote location and perform reporting tasks on the study. This functionality pertains to a physical client, which is registered for use inside or outside the hospital. Note that images are copied to the remote location, but there is no streaming between the device and client for remote locations.
Browser-based Clinical Reporting (thin client)	Same as predicate device.	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.
Other		
System access	Same as predicate device.	Define user rights based on institute level.
Single access to configuration	Same as predicate device.	Configure Philips IntelliSpace Cardiovascular in a singular place.
Tooling (user-configuration)	In addition to existing predicate device capabilities, additional tooling added for user-configuration capabilities.	User-configuration capabilities.

4. **Performance Data**

The following performance data were provided in support of the substantial equivalence determination.

a. Summary of non-clinical testing

Philips 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
- User & product specifications
- Verification & validations

b. Summary of clinical testing

The subject device of this premarket submission, Philips IntelliSpace Cardiovascular software 9.1 did not require clinical studies to support equivalence.

5. Conclusions drawn from the non-clinical and clinical testing

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

6. Conclusion

Philips IntelliSpace Cardiovascular 9.1 (subject device) is substantially equivalent to the previously cleared Philips IntelliSpace Cardiovascular 2.0 (predicate device [K153022]). The subject device has the same intended use as the predicate device. The technological and clinical characteristics are not the same, however the differences in technological and clinical characteristics between the two devices do not raise different questions of safety and effectiveness.