May 31, 2018

Philips Medical Systems Nederland BV
% Chandrika Srinivasan
Senior Regulatory Affairs Specialist
Veenpluis 4-6
5684PC Best,
THE NETHERLANDS

Re: K181177
Trade/Device Name: Interventional Workspot
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, OWB
Dated: April 30, 2018
Received: May 2, 2018

Dear Chandrika Srinivasan:

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.
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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181177

Device Name
Interventional Workspot

Indications for Use *(Describe)*

The Interventional Workspot has the following medical purpose:
• import, export and storage of digital clinical images,
• manage the patient information associated with those images.

Patient Population:
Not applicable because Interventional Workspot is only a hosting platform.

Operating Profile:
The operator of the Interventional Workspot has basic understanding of the operating principle of medical computer software.

Clinical Environment:
The software can be used in the control room and in the exam room of an interventional suite and/or operating room.

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

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

Date Prepared:	May 24, 2018	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Chandrika Srinivasan Regulatory Affairs Officer Phone: +9180 41894132 E-mail: chandrika.s@philips.com	
Secondary Contact Person:	Marta Walker Head of Regulatory Affairs IGT Systems Phone: +31 631978546 E-mail: marta.walker@philips.com	
Device:	Trade Name:	**Interventional Workspot**
	Release Number:	Version 1.4.5.1
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code: Secondary Product Code:	LLZ (System, Image Processing, Radiological) OWB (Interventional Fluoroscopic X-Ray system)
Predicate Device:	Trade Name:	*Interventional Workspot Release 1*
	Manufacturer:	Philips Medical Systems Nederland B.V
	510(k) Clearance:	K121296 (Jan 02, 2013)
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code: Secondary Product Code:	LLZ (System, Image Processing, Radiological) OWB (Interventional Fluoroscopic X-Ray system)

Device description: The Interventional Workspot is a software platform to host Interventional Tools. It provides common functionalities (e.g. import / export and data handling functions) that are required by the Interventional Tools to support the physician with performing the interventional procedure.

The images made with the Interventional Tools use X-ray imaging and CT/MR imaging as the source data, acquired on compatible equipment. The Interventional Workspot acts as a data handler for Interventional tools.

Interventional Workspot can be used with compatible Philips interventional X-ray systems that is equipped with appropriate options. Interventional Workspot is only intended to be used with the PC hardware configuration on which it is initially installed by the manufacturer.

Indications for Use: **Interventional Workspot** is provided as accessory to the Philips Interventional X-ray system, has the following indications for use:

Indications for use/ Medical Purpose:
The Interventional Workspot has the following medical purpose:
• import, export and storage of digital clinical images,
• manage the patient information associated with those images.

Patient Population:
Not applicable because Interventional Workspot is only a hosting platform.

Operating Profile:
The operator of the Interventional Workspot has basic understanding of the operating principle of medical computer software.

Clinical Environment:
The software can be used in the control room and in the exam room of an interventional suite and/or operating room.

Table 1: Indications for Use comparison with predicate device

Interventional Workspot R1.0 (predicate device) (K121296)	**Interventional Workspot R1.4.5.1 (proposed device)**	**Comparison**
The Interventional Workspot has the following medical purpose: • import, export and storage of digital clinical images, • manage the patient Information associated with those images	The Interventional Workspot has the following medical purpose: • import, export and storage of digital clinical images, • manage the patient information associated with those images	Same

The Indications for use is same for both the predicate and proposed device.

Technological characteristics:

Interventional Workspot software is executed on a PC based hardware platform.

There is no difference is Technological characteristics between the Interventional Workspot Rel. 1.0 and the proposed **Interventional Workspot IW1.4.5.1.**

Table 2: Technological characteristics comparison-Classification & Design attributes and functionality

Parameter	**Interventional Workspot R1 (K121296)** 21 CFR sec.892.2050	**Interventional Workspot R1.4.5.1 (proposed device)** 21 CFR sec.892.2050	**Comparison**
Technological characteristics	The interventional workspot is a software platform to host Interventional Tools. It provides common functionalities (e.g. import / export and data handling functions) that are required by the Interventional Tools to support the physician with performing the interventional procedure.	The interventional workspot is a software platform to host Interventional Tools. It provides common functionalities (e.g. import / export and data handling functions) that are required by the Interventional Tools to support the physician with performing the interventional procedure.	Same
Operating System	Windows XP professional	Windows 7	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
DICOM	DICOM compatible	DICOM compatible	Same
Compatibility with currently marketed Philips Interventional X-ray systems.	Compatible with currently marketed Philips Interventional X-ray systems- Allura Series.	Compatible with currently marketed Philips Interventional X-ray systems- Allura Series & Azurion series.	Substantially equivalent. Note: for ease of review, the differences have been underlined. SE analysis: Both the predicate and proposed device are accessories to the Philips

			Interventional X-ray systems.
Hardware obsolescences	-	Changes to support different hardware such as: PC Dell T3600, Haswell PC, Radysis 7 &8	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
Bug fixes	-	Minor bug fixes	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
OS & network security features	-	Changes to support network security features like whitelisting, and technology to protect malware.	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
Feature enhancement	-	Changes to support resizing larger data sets; Support for direct upgrade from older versions, software installer	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
Code refactoring	-	Code refactoring to improve software maintenance.	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.
Labeling changes	-	Adapting the labeling to include the minor changes implemented.	Substantially equivalent. SE analysis: The predicate and proposed device are same in design,

			function and application.
Support for new Interventional tools	-	Hosting platform when new Interventional tools are released.	Substantially equivalent. SE analysis: The predicate and proposed device are same in design, function and application.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the modified **Interventional Workspot R1.4.5.1** and demonstrates compliance with the following FDA recognized consensus standards and FDA guidance documents:

- IEC 62304:2006 Medical device software - Software life cycle processes. FDA/CDRH recognition number 13-32;
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.0 including corrigendum, 2015). FDA/CDRH recognition number 5-114;
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40;
- ISO15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (Second edition, 2012). FDA/CDRH recognition number 5-90;
- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016). FDA/CDRH recognition number 12-300
- *"Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"*, May 11, 2005 (document number 337);
- *"Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices"*, February 3, 2016 (document number 1757);
- *"Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"*, October 2, 2014 (document number 1825);
- *"Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]",* July 28, 2014 (document number 1766).
- Guidance for Industry, FDA Reviewers and Compliance on "Guidance for Off-the-Shelf Software Use in Medical Devices, September 1999"

Software verification testing has been performed to verify the modifications as per predetermined System Requirements Specification and acceptance critera.The verification tests and acceptance criteria were identified based on Risk Assessent. Verification tests were performed to verify safety risk control measures from the Detailed Risk Management Matrix and to verify the Privacy and Security

requirements for **Interventional Workspot 1.4.5.1.** have been implemented. Verification results demonstrated that all executed tests were passed.

Non clinical software validation testing has been performed to validate the intended use, claims, user needs, service user needs, effectiveness of safety messures and Instructions for use.

Software validation testing has been performed to validate that **Interventional Workspot** conforms to its intended use, claims and user needs.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **Interventional Workspot**:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents, and
- meets the acceptance criteria and is adequate for its intended use.

Based on the information provided above, **Interventional Workspot Release 1.4.5.1** is substantially equivalent to the predicate device *Interventional Workspot Release 1.0 (K121296)* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

Clinical images are not necessary to establish substantial equivalence based on the modifications to the predicate device (note that the Interventional Workspot software is strongly based on the predicate). Non-clinical performance data provides sufficient evidence that the subject device works as intended.

Substantial Equivalence Conclusion:

Interventional Workspot Release 1.4.5.1 is substantially equivalent to the predicate device *Interventional Workspot Release 1.0 (K121296)* in terms of indications for use, technological characteristics and safety and effectiveness.

The modifications made in the proposed device **Interventional Workspot Release 1.4.5.1** are within the controls and predetermined specifications.
Additionally, non-clinical performance tests provided in this 510(k) premarket notification demonstrated substantial equivalence to the predicate device and ensured that the modifications are implemented successfully. Verification and Validation tests were conducted to verify the modifications listed and conformance to international and FDA-recognized consensus standards and guidance documents were provided. These tests demonstrate that **Interventional Workspot Release 1.4.5.1** is substantially equivalent to the predicate device and is as safe and effective as its predicate device and does not raise any new safety and/or effectiveness concerns.