Philips Medical Systems, Nederland B.V.
℅ Maria Silos Viu
Regulatory Affairs Specialist
Veenpluis 4-6
Best, Noord-Brabant 5684 PC
THE NETHERLANDS

February 9, 2021

Re: K201583
Trade/Device Name: SmartCT
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAK, LLZ,
Dated: January 12, 2021
Received: January 15, 2021

Dear Maria Silos Viu:

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/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 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201583

Device Name
SmartCT

Indications for Use *(Describe)*
SmartCT assists physicians during vascular and non-vascular procedures, with diagnosis, treatment planning, interventional procedures and treatment follow-up by creating 3D views from sets of 2D images created during rotational acquisitions.

SmartCT provides high-speed and high-resolution 3D visualizations of vasculature, hemorrhages, soft tissue and bone structures.

SmartCT provides live image guidance for navigating endovascular devices through vascular structures anywhere in the body.

SmartCT helps to assess anatomical information intra-procedurally, such as the estimate of a vessel or lesion size, diameter or volume, and anatomical distances between relevant structures.

SmartCT is intended to be used for human patients that have been elected for the procedures as described in the Indications for Use.

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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K201583

510(k) Summary SmartCT

The 510(k) Summary of the proposed SmartCT is provided in the following pages.

510(k) Summary

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

Date Prepared:	**June 08, 2020**	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	María Silos Viu Regulatory Affairs Specialist Phone: +31 618596430 E-mail: maria.silos@philips.com	
Secondary Contact Person:	Michael Konings Director of Regulatory Affairs Phone: +31 646941461 E-mail: michael.konings@philips.com	
Device:	Trade Name:	**SmartCT**
	Classification Name:	Interventional fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Primary Code: OWB Subsequent Codes: JAK, LLZ
Primary Predicate Device:	Trade Name:	*XperCT*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K130893 (September 6, 2013)
	Classification Name:	Interventional fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	Primary Code: OWB Subsequent Code: JAK

Additional Predicate Devices:

Trade Name:	*Allura 3D-RA*
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K121772 (March 21, 2013)
Classification Name:	Interventional fluoroscopic x-ray system
Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: OWB Subsequent Codes: JAK, LLZ

Trade Name:	*3D Roadmap*
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K121772 (March 21, 2013)
Classification Name:	Interventional fluoroscopic x-ray system
Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: OWB Subsequent Codes: JAK, LLZ

Device description:

SmartCT is a 3D image visualization and analysis software product (Interventional Tool) intended to provide fast and high-resolution 3D visualization of vasculature, hemorrhages, soft tissue and bone structures, thereby helping the physician to identify pathologies and supporting the physician to define and plan the intervention strategy.

SmartCT runs on a software platform called the *Interventional Workspot*, and is intended to be used with a Philips Interventional X-Ray System.

SmartCT supports 3D Rotational Angiography (3DRA), Cone Beam CT (CBCT) and VasoCT acquisition protocols, and it includes 3D roadmap functionality. The CBCT and VasoCT protocols are only available for the 20" detector of the Interventional X-Ray system. The 3DRA protocols are available for all detectors.

The 3DRA protocols are available with *SmartCT Angio*, the CBCT protocols with *SmartCT Soft Tissue* and the VasoCT protocols with *SmartCT Vaso*. The 3D roadmap functionality (*SmartCT Roadmap*) comes in combination with *SmartCT Angio*, *SmartCT Soft Tissue* or *SmartCT Vaso*.

SmartCT includes filters to improve the image quality of the reconstruction by reducing the noise caused by metal objects or other objects that absorb high levels of X-ray radiation.

SmartCT provides overlays of live 2D fluoroscopic images with a 3D reconstruction of the vessel tree.

SmartCT offers tools to manually measure sizes and volumes of anatomical structures such as lesions, aneurysms or vessels. It also offers a vessel analysis tool that provides semi-automatic measurements of the diameter of a segmented vessel.

SmartCT can be controlled from both the control room and the examination room.

SmartCT provides workflow guidance to support the physician in the workflow of acquiring and processing 3D images.

Indications for Use:

SmartCT *assists physicians during vascular and non-vascular procedures, with diagnosis, treatment planning, interventional procedures and treatment follow-up by creating 3D views from sets of 2D images created during rotational acquisitions.*

SmartCT *provides high-speed and high-resolution 3D visualizations of vasculature, hemorrhages, soft tissue and bone structures.*

SmartCT *provides live image guidance for navigating endovascular devices through vascular structures anywhere in the body.*

SmartCT *helps to assess anatomical information intra-procedurally, such as the estimate of a vessel or lesion size, diameter or volume, and anatomical distances between relevant structures.*

SmartCT *is intended to be used for human patients that have been elected for the procedures as described in these Indications for Use.*

The indications for use of **SmartCT** are similar to the indications for use of the currently marketed predicate devices *XperCT, Allura 3D-RA* and *3D Roadmap.* Based on the information provided above, **SmartCT** is considered substantially equivalent to the currently marketed and predicate devices *XperCT, Allura 3D-RA* and *3D Roadmap* in terms of Indications for Use.

Technological characteristics:

SmartCT has similar technological characteristics compared to the predicate devices. Similar features are used in the predicate and subject devices, with exception of the following modifications implemented in the **SmartCT**:

- 3D acquisition guidance including injector protocols suggestions and acquisition timeline showing the different phases of the 3D acquisition performed via Philips Interventional X-Ray system.
- Visualization improvements such as skull removal feature, initial viewing settings and 3D volume rendering options.
- User Interface improvements to enhance the interaction of the user with the Multi-Modality Touch Screen Module at table side and provide workflow guidance, as well as overall usability improvements, including 3D measurements and annotations.
- Architectural improvements including enhanced interface between **SmartCT** and Philips Interventional X-Ray system in order to get additional information on specific settings and acquisition protocols required for the enabling the acquisition guidance functionality.
- Curved and straightened reformat for vessel views and new implementing algorithm on Vessel Analysis tool.

The differences between **SmartCT** and the predicate devices do not raise any new questions regarding safety or effectiveness. Based on the information provided above, **SmartCT** is considered substantially equivalent to the currently marketed and predicate devices *XperCT, Allura 3D-RA and 3D Roadmap* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **SmartCT** and demonstrates compliance with the following FDA recognized consensus standards:

- IEC 62304 *Medical device software – Software life cycle processes* (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79.
- IEC 62366-1 *Medical devices - Part 1: Application of usability engineering to medical devices* (Edition 1.0, 2015-02). FDA/CDRH recognition number 5-114.
- IEC 82304-1 *Health software – Part 1: General requirements for product safety* (Edition 1.0 2016-10), FDA/CDRH recognition number 13-97.
- ISO 14971 *Medical devices – Application of risk management to medical devices* (Edition 2.0, corrected 2007). FDA/CDRH recognition number 5-40.
- ISO 15223-1 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements* (Third Edition, 2016-11-01). FDA/CDRH recognition number 5-117.
- UL 2900-1, *Standard For Safety, Standard For Software Cybersecurity Network-Connectable Products, Part 1: General Requirements, (*First Edition, 2017-08), FDA/CDRH recognition number 13-96
- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016-06). FDA/CDRH recognition number 12-300
- IEC 80001-1 Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities (Edition 1.0, 2010-10). FDA/CDRH recognition number 13-38.

Software verification testing of the functional and non-functional requirements as well as performance, reliability and safety has been performed to verify that all the requirements of System Requirements Specification as well as the safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements and mitigations have been implemented. Results demonstrated that all executed verification tests were passed.

Non-clinical validation testing has been performed to validate that **SmartCT** conforms to the intended use, claims, user needs, effectiveness of safety measures and instructions for use. The validation consisted of the following activities:

- Usability validation was performed with representative clinical users (both physicians and nurse/technicians) in a simulated use environment. **SmartCT** was found to be safe and effective for the intended use, users and use environment

- A simulated use design validation was undertaken with participants who fulfill the intended user profile. The participants executed validation protocols in the form of a clinical workflow to validate user needs, intended use and claims. Results demonstrated that all executed validation protocols were passed.

- A clinical experience (expert opinion) evaluation was performed in order to validate some marketing claims and user needs regarding the clinical

functionality of **SmartCT** by assessing clinical images. Results demonstrated that these commercial claims and user needs were successfully validated.

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

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

Therefore, **SmartCT** is substantially equivalent to the predicate devices *XperCT, Allura 3D-RA and 3D Roadmap* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed **SmartCT** did not require clinical study since substantial equivalence to the currently marketed and predicate devices *XperCT, Allura 3D-RA and 3D Roadmap* was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The **SmartCT** is substantially equivalent to the currently marketed predicate devices *XperCT* (K130893), *Allura 3D-RA and 3D Roadmap* (K121772) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) pre-market notification. These tests demonstrate that **SmartCT** complies with the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.