August 17, 2018

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

Re: K181966
Trade/Device Name: SmartPerfusion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Codes: OWB, LLZ
Dated: July 20, 2018
Received: July 23, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*
K181966

Device Name
SmartPerfusion

Indications for Use *(Describe)*

SmartPerfusion assists in the diagnosis of perfusion alterations of tissues based on digital subtraction angiography (DSA) and can be used for any location in the body where DSA is used.

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:	Aug 14, 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:	**SmartPerfusion**
	Release Number:	Release 1.0
	Classification Name:	Image intensified fluroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional Fluoroscopic X-Ray system)
	Secondary Product Code:	LLZ (System, Image Processing, Radiological)
Predicate Device:	Trade Name:	2D Perfusion
	Manufacturer:	Philips Medical Systems Nederland B.V
	510(k) Clearance:	K132147 (Dec 16, 2013)
	Classification Name:	Image intensified fluroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional Fluoroscopic X-Ray system)
	Secondary Product Code:	LLZ (System, Image Processing, Radiological)

Device description:	**SmartPerfusion** is a software product (Interventional Tool) that provides color coded representation of a digital subtraction angiography (DSA). It can visualize multiple functional parameters related to the time density function. It also provides a comparison between pre-, peri-, and post-procedural color coded images. **SmartPerfusion** is provided as an accessory to the Philips Interventional X-ray system.
Indications for Use:	SmartPerfusion assists in the diagnosis of perfusion alterations of tissues based on digital subtraction angiography (DSA) and can be used for any location in the body where DSA is used.
Patient Population	SmartPerfusion is suitable for use with the entire human population.
Intended Operator Profile	The Operator is a physician or other qualified healthcare professional who is fully skilled and responsible for sound clinical judgment and for applying the best clinical procedure, for example: • Interventional radiologist • Interventional neuro-radiologist • Vascular surgeon and Podiatrists • Interventional Cardiologist • Skilled radiology technician (or nurse) assisting the physician • Oncologist
General safety and effectiveness	To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the device labeling, as well as training at system handover.
Clinical Environment:	SmartPerfusion can be used in the control room and in the exam room of an interventional suite or operating room. SmartPerfusion is a software application and does not come in contact with the patient.

Table 1: Indications for Use comparison with predicate device

Predicate device 2D Perfusion (K132147)	Proposed device SmartPerfusion	Comparison
2D Perfusion assists in the diagnosis of perfusion alterations of tissues, based on digital subtraction angiography (DSA) by providing color coded images generated from the DSA series.	SmartPerfusion assists in the diagnosis of perfusion alterations of tissues based on digital subtraction angiography (DSA) and can be used for any location in the body where DSA is used.	***Identical, Substantially equivalent*** Note: for ease of review, the differences have been underlined. **SE analysis:** The additional sentence is to improve clarity of the use of device.

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

Technological characteristics:

There are differences in Technological characteristics between the predicate device 2D Perfusion (K132147) and the proposed device **SmartPerfusion**, however those different technological characteristics have been demonstrated to not affect a determination of Substantial Equivalence.

The following table provides comparison of the Technological characteristics.

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

Parameter	Predicate device 2D Perfusion (K132147)	Proposed device SmartPerfusion	Conclusion
Compatibility with currently marketed Philips X-ray systems	Is a software accessory to currently marketed Philips Allura and Azurion Interventional X-ray system (K172822, K162859)	same	***Substantially equivalent.***
Image input	Uses angiography X-ray images as input	same	***Substantially equivalent.***
Anatomy	Anatomical area – General vasculature. Not anatomy specific	same	***Substantially equivalent***

Parameter	Predicate device 2D Perfusion (K132147)	Proposed device SmartPerfusion	Conclusion
Core Algorithm & Quantification	Algorithm for generation of functional images	Same	***Substantially equivalent***
Parameters provided to the user	1. Arrival Time 2. Time to Peak (TTP) 3. Wash-in Rate 4. Width 5. Area under Curve (AuC) 6. Mean Transit Time (MTT)	Same for parameters 1 to 6. Additional 2 parameters are provided. **7. <u>Wash out Rate:</u>** The Wash-out Rate is defined by the slope of the wash-out curve. The Wash-out Rate gives an indication of the flow rate. **8. <u>Peak density</u>** The Peak Density is the highest density value of the time density curve.	***Substantially equivalent*** **SE analyis:** The additional parameters 7 & 8 are also derived from the same algorithm. These parameters are not used for Clinical decision making.
Instant Overview	Functional parameters are displayed for a region of interest based on functional parameters selected.	All functional parameters are displayed instantly in one screen.	***Substantially equivalent*** **SE analyis:** All functional parameters are shown at once to improve user experience.
Configurable parameters	Not provided.	Among the available parameters, user can sub-select the parameters that will be displayed on the screen.	***Substantially equivalent*** **SE analyis:** User is provided with an option to choose the parameters to be shown to improve User experience.
Feature comparison: **Color coded image**	Provides color coded representation of a digital subtraction angiography (DSA) run.	Same with additional color coded image for Wash out rate is shown.	***Substantially equivalent*** **SE analyis:** Both the products use the same algorithm. Additional color coded image for wash out rate is also derived from the same Time Density curve.
On screen help	Not provided.	On screen acquisition guidance is provided.	***Substantially equivalent*** **SE analysis:** SmartPerfusion displays on screen help/guidance to the user to improve workflow.

Parameter	Predicate device 2D Perfusion (K132147)	Proposed device SmartPerfusion	Conclusion
Comparison View	Provides a side by side comparison between pre-, peri-, and post-procedural color coded images and quantified functional parameters. Provides visualization of contrast density over time in a graphical format for a user-defined region of interest	Same with additional option for peripheral acquisitions to compare 3 series at the same time.	***Substantially equivalent*** **SE analysis:** The additional viewing option is provided for ease of use.
Imaging tools	Provides basic image tools (zoom, pan, contrast/brightness) to manipulate image data that is shown in the viewers	same	***Substantially equivalent***
ROI	Provides a mechanism to the user to mark a region of interest on an X-ray run within which all the flow parameters derived by analyzing contrast density over time are computed.	Same with additional ROI drawing options like automatic ROI that are user editable,manual ROI, multiple ROI, different ROI shapes/free form ROI/user defined ROI.	***Substantially equivalent*** **SE analysis:** SmartPerfusion provides additional options to improve user experience.
Snapshot	Provides a mechanism to the user to take a snapshot of the main display area. The snapshot is stored as a JPEG image (compatible with DICOM Secondary Capture), and can be selected in the Export activity for export to another workstation or medium	Same with additional option to take a snapshot of the whole screen.	***Substantially equivalent*** **SE analysis:** Both tools provide the functionality to take snapshots. Along with main display area, SmartPerfusion also provides a mechanism to take a snapshot of the whole screen. In both kinds of snapshots, the data is stored in the same format. This additional mechanism is a non-mandatory part of the clinical workflow and only helps the user in also capturing task panel and all viewports in a single snapshot.

Parameter	Predicate device 2D Perfusion (K132147)	Proposed device SmartPerfusion	Conclusion
Export	Provides a mechanism to export the currently displayed time density curves to USB removable drive	Same with additional information of functional parameter values for ROI.	***Substantially equivalent*** **SE analysis:** Additional information is also exported.
Overlay pre-series & Recall catheter image	Not provided.	Provides functionality to achieve the same anatomical positioning in a new DSA run as a previously acquired DSA run. Provides functionality to store and recall the image of the catheter position to make sure the runs are comparable	***Substantially equivalent*** **SE analysis:** This additional functionality helps the interventionalist in achieving the same catheter & anatomical position as pre series before acquisition of the peri- or post- series. This is a non-mandatory part of the product workflow.
APC	Not provided.	Provides functionality to auto-recall X-ray view orientations used to achieve the same X-ray view orientation as the loaded pre-series.	***Substantially equivalent*** **SE analysis:** This additional functionality is a non-mandatory part of the clinical workflow.
Table side interaction	Not provided.	Table side interaction is provided through Touch screen module.	***Substantially equivalent*** **SE analysis:** This additional functionality improves user experience. This is a non-mandatory part of the clinical workflow.
Software Architecture improvements	Not provided.	Architecture improvements to facilitate software maintenance, reduce launch time for acquisition guidance, easy portability on the hosting platform, more memory efficient, ability to handle more number of frames.	***Substantially equivalent*** **SE analysis:** These technical changes do not affect the clinical workflow.
Software platform	*2D Perfusion* is a software medical device, which runs on Interventional Workspot (K181177).	Same	***Substantially equivalent***

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed device **SmartPerfusion** and the proposed device demonstrates compliance with the following FDA recognized consensus standards and FDA guidance documents:

- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes. FDA/CDRH recognition number 13-79;
- IEC 62366-1 Edition 1.0 2015-02 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 Second Edition 2007-03-01 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40;
- ISO15223-1 Third Edition 2016-11-01 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement. FDA/CDRH recognition number 5-117;
- 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 pre-determined System Requirements Specification and acceptance criteria.The verification tests and acceptance criteria were identified based on Risk Assessent. Cybersecurity risks were assessed and privacy and Security requirements were identified and 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 **SmartPerfusion** 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 **SmartPerfusion** 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 **SmartPerfusion**:

- 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, the proposed device **SmartPerfusion** is substantially equivalent to the predicate device 2D Perfusion *(K132147)* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

SmartPerfusion does not require a clinical study as the substantial equivalence with the predicate device 2D Perfusion *(K132147)* is demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing, including safety and effectiveness.

Non-clinical performance data provides sufficient evidence that the subject device works as intended

The verification and validation test results of the modified device **SmartPerfusion** described above support the safety and effectiveness of the product. It conforms to the intended use, the user needs and the claims and is therefore considered substantially equivalent to the predicate device 2D Perfusion *(K132147)*.

Substantial Equivalence Conclusion:

SmartPerfusion is substantially equivalent to the predicate device 2D Perfusion *(K132147)* in terms of indications for use, technological characteristics and safety and effectiveness.

The modifications made in the proposed device **SmartPerfusion** 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 **SmartPerfusion** 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.