



Philips Medical Systems Nederland B.V.
% Ms. Laura Wortel
Regulatory Affairs Officer
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

October 24, 2017

Re: K172307

Trade/Device Name: Dynamic Coronary Roadmap 2.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: July 28, 2017
Received: July 31, 2017

Dear Ms. Wortel:

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 (DICE) 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 (DICE) 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,

 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)

K172307

Device Name

Dynamic Coronary Roadmap 2.0

Indications for Use (Describe)

Dynamic Coronary Roadmap is intended to assist the physician during percutaneous coronary interventions in correlating the device position to the coronary vasculature, by providing a motion compensated overlay of this coronary vasculature.

The FFR/iFR Roadmap feature is intended to assist the physician during percutaneous coronary interventions in relating the intravascular blood pressure measurement to its anatomical location. FFR/iFR roadmap visualizes the position of the pressure wire and the coronary artery on an X-ray image at the moment that an intravascular blood pressure measurement was performed as well as the intravascular blood pressure measurement values themselves.

Dynamic Coronary Roadmap is suitable for use with the entire adult human population.

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

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

Date Prepared: July 28, 2017

Manufacturer: Philips Medical Systems Nederland B.V.
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Device:

Trade Name:	Dynamic Coronary Roadmap 2.0
Classification Name:	Image-intensified fluoroscopic 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:	<i>Dynamic Coronary Roadmap 1.0</i>
Manufacturer:	Philips Medical Systems Nederland B.V
510(k) Clearance:	K170130 (Jun 02, 2017)
Classification Name:	Image-intensified fluoroscopic 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: Dynamic Coronary Roadmap is a software medical device intended to provide a real-time and dynamic angiographic roadmap of coronary arteries.

The angiographic roadmap is automatically generated from previously acquired diagnostic coronary angiograms during the same procedure.

Dynamic Coronary Roadmap overlays the angiographic roadmap on live 2D fluoroscopic images, thereby assisting the physician in navigating devices, e.g. (guide) wires, catheters, through the coronary arteries.

Dynamic Coronary Roadmap is to be used in combination with a Philips Interventional X-ray system.

When also used in conjunction with a compatible intravascular blood pressure measurement system, Dynamic Coronary Roadmap offers an FFR / iFR Roadmap feature. This feature co-registers the information of the blood pressure within a coronary artery with the corresponding X-ray image of the pressure wire within that coronary artery.

Dynamic Coronary Roadmap is compatible with the following intravascular blood pressure measurement systems:

- Philips Volcano CORE systems containing the FFR v 2.5 modality; and
- Philips Volcano CORE Mobile systems containing the FFR v 2.5 modality.

Indications for Use: **Dynamic Coronary Roadmap 2.0**, provided as accessory to the Philips Interventional X-ray system, has the following indications for use:

Dynamic Coronary Roadmap is intended to assist the physician during percutaneous coronary interventions in correlating the device position to the coronary vasculature, by providing a motion compensated overlay of this coronary vasculature.

The FFR / iFR Roadmap feature is intended to assist the physician during percutaneous coronary interventions in relating the intravascular blood pressure measurement to its anatomical location. FFR / iFR roadmap visualizes the position of the pressure wire and the coronary artery on an X-ray image at the moment that an intravascular blood pressure measurement was performed as well as the intravascular blood pressure measurement values themselves.

Dynamic Coronary Roadmap is suitable for use with the entire adult human population.

The indications for use of **Dynamic Coronary Roadmap 2.0** are similar to the indications for use of the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)*.

Both devices are

- indicated to assist the physician during percutaneous coronary interventions in correlating the device position to the coronary vasculature, by providing a motion compensated overlay of this coronary vasculature; and
- suitable for use with the entire adult human population.

The only difference is that the Indications for Use of **Dynamic Coronary Roadmap 2.0** has been further detailed by adding a description of the FFR / iFR Roadmap feature.

Technological characteristics:

The further detailing does not raise any new safety and effectiveness questions since **Dynamic Coronary Roadmap 2.0** still has the same intended use as the predicate device: both devices are accessories to the currently marketed Philips Interventional X-ray systems and provide real-time image guidance in the form of a motion compensated overlay of the coronary vasculature.

Based on the information provided above, **Dynamic Coronary Roadmap 2.0** is considered substantially equivalent to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)* in terms of Indications for Use.

Dynamic Coronary Roadmap 2.0 employs comparable technology as implemented in the currently marketed predicate device, *Dynamic Coronary Roadmap 1.0 (K170130)*.

The technological similarities are listed below:

Both devices

- use an enhanced roadmap on the guidance monitor overlaying a roadmap fused with live fluoroscopic images to provide real time image guidance;
- construct the enhanced coronary roadmap from a 2D diagnostic coronary angiogram;
- select the right roadmap image from the cardiac cycle and position it based upon the catheter tip;
- overlay dynamic structures and compensate for cardiac motion;
- provide X-ray system integration, including:
 - Automatically powering ON and OFF with the X-ray system.
 - 3D Automatic Position Control (APC); this allows the C-arm to automatically move to a nearby available dynamic angiographic roadmap to be able to reuse this for live guidance.
 - Table-side control.
- provide archiving of images to DICOM compatible devices.

There is only one technological difference with the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)*:

- **Dynamic Coronary Roadmap 2.0** provides a FFR / iFR Roadmap feature. This feature automatically co-registers the imported intravascular (FFR or iFR) blood pressure data from a compatible intravascular blood pressure measurement system (Philips Volcano CORE systems containing the FFR v 2.5 modality or Philips Volcano CORE Mobile systems containing the FFR v 2.5 modality) with the corresponding X-ray data based on a time synchronization mechanism.

This difference between **Dynamic Coronary Roadmap 2.0** and the predicate device does not raise any new questions regarding safety and effectiveness. Based on the information provided above, **Dynamic Coronary Roadmap 2.0** is considered substantially equivalent to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)* in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **Dynamic Coronary Roadmap 2.0** and demonstrates compliance with the following FDA recognized consensus standards and FDA guidance documents:

- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1, 2015). FDA/CDRH recognition number 13-79;
- 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).

Non-clinical verification and validation testing has been performed for **Dynamic Coronary Roadmap 2.0**. The focus of the verification and validation testing was on the FFR / iFR Roadmap feature, as this was the main change compared to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)*.

Software verification testing has been performed to verify that all requirements of the System Requirements Specification as well as the identified safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements for **Dynamic Coronary Roadmap 2.0** have been implemented. Results demonstrated that all executed tests were passed.

Algorithm verification was not warranted as there are no algorithms implemented for the FFR/iFR Roadmap feature and no changes have been made to the existing Roadmapping algorithm that impacted its performance compared to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)*.

Software validation testing has been performed to validate that **Dynamic Coronary Roadmap 2.0** conforms to its intended use, claims and user needs. The validation consisted of the following activities:

- Usability validation was performed with certified interventional cardiologists in a simulated environment. Mean task completion rates, system usability scores and net promotor scores exceeded the predefined criteria;
- Expert opinion validation was performed in a simulated environment where certified interventional cardiologists analyzed a wide range of pre-clinical datasets. The actual acceptance scores exceeded the predefined acceptance criteria;
- In-house simulated use validation was performed with experienced Clinical Marketing specialists that fulfill the intended user profile based on their clinical knowledge gained from work experience and hospital visits. The participants executed validation protocols in the form of a device navigation workflow to validate user needs, intended use and effectiveness of the safety and security related measures. Results demonstrated that all executed validation protocols were passed.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **Dynamic Coronary Roadmap 2.0**:

- 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, **Dynamic Coronary Roadmap 2.0** is substantially equivalent to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

Dynamic Coronary Roadmap 2.0 did not require a clinical study since substantial equivalence to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)* was demonstrated with the following attributes:

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

The verification and validation test results of **Dynamic Coronary Roadmap 2.0** 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 currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)*.

Substantial Equivalence Conclusion:

Dynamic Coronary Roadmap 2.0 is substantially equivalent to the currently marketed predicate device *Dynamic Coronary Roadmap 1.0 (K170130)* 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) premarket notification. These tests demonstrate that **Dynamic Coronary Roadmap 2.0** complies with the user need requirements as well as the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device and does not raise any new safety and/or effectiveness concerns.