Philips Medical Systems Nederland B.V.  
Elaine Alan  
Regulatory Affairs Specialist  
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The Netherlands  

Re: K170130  
Trade/Device Name: Dynamic Coronary Roadmap  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-Intensified Fluoroscopic X-Ray System  
Regulatory Class: Class II  
Product Code: OWB, LLZ  
Dated: April 28, 2017  
Received: May 1, 2017  

June 2, 2017

Dear Elaine Alan:

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 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 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,

[Signature]

Robert A. 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

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. Dynamic Coronary Roadmap is suitable for use with the entire adult human population. Dynamic Coronary Roadmap is a software medical device and does not come in contact with a human subject.

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: April 4, 2017

Manufacturer: Philips Medical Systems Nederland B.V.
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Device:
Trade Name: Dynamic Coronary Roadmap
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: 3D Roadmap Rel. 1
Manufacturer: Philips Medical Systems Nederland B.V.
510(k) Clearance: K121772 (March 21, 2013)
Classification Name: Image-intensified fluoroscopic x-ray system
Classification Regulation: 21 CFR, Part 892.1650
Classification Panel: Radiology
Device Class: Class II
Product Code: OWB, LLZ
Device Description:

The 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 uses coronary angiograms, acquired during a PCI procedure, to automatically generate a dynamic angiographic roadmap of the coronary vasculature. This roadmap is then overlaid on the live fluoroscopy images during device navigation. Dynamic Coronary Roadmap works in combination with a Philips interventional X-ray system. The user interface of Dynamic Coronary Roadmap guides the physician through the workflow and minimal additional user interaction from the tablesde is required. The following design features support the physician with this:

- **Dynamic angiographic roadmap creation;** this technique allows the physician to automatically construct a 2D dynamic angiographic roadmap of the coronary vasculature from a diagnostic coronary angiogram.
- **Live guidance;** this technique provides continuous overlay of the dynamic angiographic roadmap on live fluoroscopic images.
- **X-ray system integration;** this provides the physician with a seamless integration with the Philips interventional X-ray system. The clinical product supports:
  - Automatic power ON or OFF; this allows the software medical device to always be available by 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; this provides the physician with an efficient workflow during interventional procedures. The most frequently used functions that require additional user interaction next to the normal x-ray system interaction can be controlled from the tablesde of the X-ray system.

Indications for Use:

Dynamic Coronary Roadmap, 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.*

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

*Dynamic Coronary Roadmap is a software medical device and does not come in contact with a human subject.*
The indications for use of Dynamic Coronary Roadmap are similar to the currently marketed and predicate device 3D Roadmap Rel. 1.

Both devices provide image overlay of the anatomic region of interest to assist in visualizing device positioning in the vasculature during fluoroscopic procedures. The difference between the medical devices lies in the nature of the 2D/3D image input data used in combination with the live fluoroscopy. For the physician the difference does not affect the clinical procedure because at any given moment a live fluoroscopic image is displayed on a 2D view of the vasculature. Both devices have the same intended use: they are accessories to the currently marketed Philips interventional X-ray systems and provide real time image guidance.

Based on the information provided above, Dynamic Coronary Roadmap is substantially equivalent to the predicate device 3D Roadmap Rel. 1 in terms of Indications for Use.

**Technological Characteristics:**

Dynamic Coronary Roadmap employs comparable technology as implemented in the predicate device, 3D Roadmap Rel. 1:
- Both tools use an enhanced roadmap on the guidance monitor overlaying a roadmap fused with live fluoroscopic images,
- Both tools use pre-acquired angiography data as input for the overlay, and
- Both tools use X-ray system geometry information to match the data (position, scaling).

The technological differences between Dynamic Coronary Roadmap and the 3D Roadmap Rel. 1 are noted below:
- In Dynamic Coronary Roadmap the (enhanced) coronary roadmap is constructed from a 2D diagnostic coronary angiogram instead of a 3D volume created from a rotational angiogram;
- In Dynamic Coronary Roadmap the (enhanced) coronary roadmap selects the right roadmap image from the cardiac cycle and positions it based upon the catheter tip.
- Dynamic Coronary Roadmap overlays dynamic structures and compensates for cardiac motion while the predicate 3D Roadmap Rel. 1 overlays static structures provides motion compensation for patient movement.

The differences between Dynamic Coronary Roadmap and the predicate device do not raise any new questions regarding safety and effectiveness. Based on the information provided above, Dynamic Coronary Roadmap is substantially equivalent to the predicate device 3D Roadmap Rel. 1 in terms of technological characteristics.
Summary of Non-Clinical Performance Data:

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

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.1, 2015-06),
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Ed. 1.0, 2015-02),
- ISO 14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, 2007),
- ISO15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (Second Edition 2012-07-01).
- 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)

The following software verification and validation activities have been performed for Dynamic Coronary Roadmap (DCR):

- General verification testing: software verification has been performed to cover the system level requirements of the System Requirements Specification as well as the identified risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements. These protocols address functional and non-functional aspects of DCR such as reliability, performance and interoperability.

- Algorithm verification testing: Dedicated algorithm verification testing has been performed with standard angiographic and fluoroscopy x-ray data to ensure sufficient functioning of the algorithms. An indirect registration verification was performed focusing only on the registration of the catheter tip and the guide wire.

General Validation Results
Non-clinical software validation testing provided evidence for the intended use, user needs and claims:

a) Usability validation: Was performed with representative intended users in a simulated environment.
b) Expert opinion Validation: The expert opinion validation was performed in a simulated environment with certified interventional cardiologists. Standard angiographic and fluoroscopy x-ray data was used to allow the expert to evaluate a wide range of variance e.g. region to treat, detector format, patient, acquisition angles.

c) In-house simulated Validation: Validation protocols were created to address each clinical user need in the form of a device navigation workflow. Additional protocols were created to ensure that the Instructions for Use is written on the correct detail level as well as the verification of the effectiveness of the safety mitigations. The protocols were executed in a simulated clinical setting. The validation protocols have been performed by experienced Clinical Marketing Specialists with clinical knowledge gained from work experience and hospital visits. All test participants have experience in the relevant clinical area and therefore are considered equivalent to the intended operator profiles as defined in the Intended use.

Summary of Clinical Performance Data:

Dynamic Coronary Roadmap did not require clinical trials to establish substantial equivalence to the predicate device 3D Roadmap Rel. 1. Substantial equivalence was demonstrated with the following attributes:

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

Verification and validation tests as described above were performed on the proposed Dynamic Coronary Roadmap according to the following FDA-recognized consensus standards and FDA guidance documents:

- 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 5-95,
- 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

Conclusion: The verification and validation test results of the Dynamic Coronary Roadmap, comprising of verification testing, usability validation, validation of the user needs and specific claims, and expert opinion validation are passed and 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 device 3D Roadmap Tel. 1.

**Substantial Equivalence Conclusion:**
Dynamic Coronary Roadmap is substantially equivalent to the currently marketed 3D Roadmap Rel. 1 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 complies with the user need requirements as well as the requirements as 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 questions.