DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 7, 2017

Philips Medical Systems Nederland B.V.
% Ms. Elaine Alan
Regulatory Affairs Specialist
Veenpluis 4-6
5684 PC Best
THE NETHERLANDS

Re: K170144
Trade/Device Name: StentBoost Live
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: May 9, 2017
Received: May 10, 2017

Dear Ms. 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,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170144

Device Name

StentBoost Live

Indications for Use *(Describe)*

StentBoost Live is intended to assist the physician during percutaneous coronary interventions.
StentBoost Live provides real-time enhanced visualization of stents.
StentBoost Live provides real-time enhanced visualization of stents in relation to coronary vessels.
StentBoost Live assists in the treatment of cardiovascular diseases by visualizing the placement and deployment of coronary stents.
StentBoost Live is suitable for use with the entire adult human population.
StentBoost Live 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.

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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: January 13, 2017

Manufacturer:
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Device:	Trade Name:	**StentBoost Live**
	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:	*StentBoost Rel. 4*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K132305 (October 30, 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:

StentBoost Live is a software medical device intended to provide enhanced visualization of stents in coronary vessels in real-time. It supports the physician in placing and deploying stents.
The **StentBoost Live** is connected to a Philips interventional X-ray System and uses X-ray generated data as input.
StentBoost Live uses radiopaque balloon markers to provide real-time stent enhanced visualization by displaying a motion compensated average stent image.
StentBoost Live provides X-ray System integration with the Philips interventional X-ray System to allow automatic power on and off of **StentBoost Live**. In addition the user interactions can be controlled from the table-side of the X-ray System.
StentBoost Live provides the option for the physician to create DICOM compatible snapshots and movies of the enhanced image for reporting and archiving when connected to a picture archiving and communication system (PACS).

Indications for Use:

StentBoost Live, provided as accessory to the Philips Interventional X-ray system, has the following indications for use:
StentBoost Live *is intended to assist the physician during percutaneous coronary interventions.*
StentBoost Live *provides real-time enhanced visualization of stents.*
StentBoost Live *provides real-time enhanced visualization of stents in relation to coronary vessels.*
StentBoost Live *assists in the treatment of cardiovascular diseases by visualizing the placement and deployment of coronary stents.*
StentBoost Live *is suitable for use with the entire adult human population.*
StentBoost Live *is a software medical device and does not come in contact with a human subject.*

The indications for use of **StentBoost Live** are similar to the currently marketed and predicate device *StentBoost Rel. 4* except that:

- The use of **StentBoost Live** is restricted to cardiovascular procedures instead of both vascular and cardiovascular procedures.
- **StentBoost Live** provides real-time enhanced visualization of stents.

However, the difference does not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the predicate device. Both devices have the same intended use: they are accessories to the currently marketed Philips Interventional X-ray system and both are X-ray interventional applications which provide enhanced visualization of stents in relation to vessels and assist in the treatment of cardiovascular diseases through visualization of the placement and deployment of coronary stents.

Based on the information provided above, **StentBoost Live** is considered substantially equivalent to the predicate device *StentBoost Rel. 4* in terms of Indications for Use.

Technological characteristics:

StentBoost Live employs comparable technology as implemented in the predicate device *StentBoost Rel. 4*:

- Both tools provide enhanced (i.e. motion-compensated average) stent visualization of both a pre and post stent deployment created from markers found in a 2D image sequence acquired on the interventional X-ray system
- Both tools provide full integration with the interventional X-ray system
- Both tools have Picture Archiving Communication System compatibility

The technological differences between **StentBoost Live** and its predicate device *StentBoost Rel. 4* are noted below:

- For *StentBoost Rel. 4* the enhanced image is only available once the acquisition is completed where for **StentBoost Live** the enhanced image visualization of the placement and deployment of the stent in the exam room is in real-time.
- *StentBoost Rel. 4* provides StentBoost Subtract mode of operation which is not needed in **StentBoost Live**.
- *StentBoost Rel. 4* provides StentBoost Vascular mode of operation which is not supported in **StentBoost Live**.
- **StentBoost Live** provides improved workflow guidance.
- **StentBoost Live** is automatically switched on and off with the X-ray system which is not available in the *StentBoost Rel 4*.
- *StentBoost Rel. 4* provides a manual measurement tool to measure the diameter of a deployed stent which is not available in the **StentBoost Live** since providing post-deployment stent measurements is not essential for the workflow. The measurement functionality is still available through other software tools provided by the Philips Interventional X-ray system.
- **StentBoost Live** can only be controlled in the exam room where *StentBoost Rel. 4* can be controlled in both the exam and control room. Due to the real-time workflow of **StentBoost Live**, use outside of the exam room is not needed.
- *StentBoost Rel. 4* allows optional manual indication of the marker position where **StentBoost Live** allows the user to indicate the marker search region using the collimation feature of the Philips interventional X-ray system.

The differences between **StentBoost Live** and the predicate device *StentBoost Rel. 4* do not raise any new questions regarding safety or effectiveness.
Based on the information provided above, **StentBoost Live** is considered substantially equivalent to the primary currently marketed and predicate device in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **StentBoost Live** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- 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).
- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016).
- 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).

The following software verification and validation activities have been performed for **StentBoost Live**:

- 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 StentBoost Live such as reliability, performance and interoperability.

- Algorithm verification testing: Dedicated algorithm verification testing has been performed with previously acquired x-ray data to ensure sufficient functioning of the algorithms. Verification consisted of determining marker pair detection performance and benchmark testing against the predicate device, StentBoost R4.

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. Previously acquired 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:

StentBoost Live did not require clinical trials to establish substantial equivalence to the currently marketed StentBoost R4. Substantial equivalence was demonstrated with the following attributes:

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

Verification and validation tests as described above were performed on the **StentBoost Live** 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 **StentBoost Live**, 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 StentBoost R4.

Substantial Equivalence

StentBoost Live is substantially equivalent to the predicate device *StentBoost Rel. 4* in terms of indications for use, technological characteristics and safety and

Conclusion: effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that **StentBoost Live** complies with 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 questions.