Philips India Limited
% Shruti Sancheti
Regulatory Approbation Officer
Plot No. B-79, MIDC, Phase-II, Chakan, Taluka-
Khed, Village - Savardari
Pune, Maharashtra 410501
INDIA

April 5, 2021

Re: K203623
Trade/Device Name: StentBoost Mobile
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, LLZ
Dated: March 2, 2021
Received: March 8, 2021

Dear Shruti Sancheti:

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,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203623

Device Name
StentBoost Mobile

Indications for Use *(Describe)*
StentBoost Mobile is intended for use as a vascular x-ray interventional application.
StentBoost Mobile provides high image quality visualization of stents in relation to vessels.
StentBoost Mobile assists in the treatment of endovascular diseases by visualizing the placement and deployment of stents.

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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K203623
510(k) Summary

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

Date Prepared: **December 8, 2020**

Manufacturer:
Philips India Limited
Plot No. B-79, MIDC, Phase-II, Chakan
Taluka - Khed, Village - Savardari
District: Pune
Maharashtra 410501
India
Establishment Registration Number: 3010685285

Primary Contact Person:
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Device:

Trade Name:	**StentBoost Mobile**
Classification Name:	Interventional fluoroscopic x-ray system
Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Regulatory Class:	Class II
Product Code:	Primary Code: OWB Subsequent Codes: LLZ

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:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: OWB Subsequent Code: LLZ

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

Device description: **StentBoost Mobile** is a software product (iApp) intended to provide a high-resolution visualization of stents in vessels. It supports the physician in placing and deploying stents.

Indications for Use: **StentBoost Mobile** is intended for use as a vascular x-ray interventional application.

StentBoost Mobile provides high image quality visualization of stents in relation to vessels.

StentBoost Mobile assists in the treatment of endovascular diseases by visualizing the placement and deployment of stents.

The indications for use of **StentBoost Mobile** is a subset of *StentBoost Rel. 4,* as **StentBoost Mobile** is intended for use as a vascular application only, and, *StentBoost Rel. 4* is used for vascular or cardiovascular applications. Based on the information provided above, **StentBoost Mobile** is considered substantially equivalent to the currently marketed and predicate device *StentBoost Rel. 4* in terms of Indications for Use.

Comparison of Technological characteristics with the Predicate Device:

The fundamental scientific technology provided in the subject device **StentBoost Mobile** and predicate device *StentBoost Rel. 4* is same based on the following:

- Image processing algorithm;
- Execution on and connection to a software hosting platform/ workstation;
- Transmission of 2D image sequence from a digital X-ray imaging system to the software hosting platform;
- Display of image series on reference monitor screen.

The differences between **StentBoost Mobile** and the predicate device are as follows:

- Predicate device *StentBoost Rel. 4* runs on the independent hosting software functionality platform of the currently marketed Philips Interventional Workspot (K121296), whereas, the subject device **StentBoost Mobile** runs on compatible platform, which is available on Philips Zenition series mobile surgery interventional X-ray systems (K183101, K183040).
- Change in the user interface and visualization components between the predicate and the subject device.
- *StentBoost Rel. 4* can be controlled from both the control room and exam room. In the exam room, *StentBoost Rel. 4* can be operated via the touch-screen module of the Allura X-ray system. On the contrary, **StentBoost Mobile** can be controlled only from the compatible Zenition series mobile surgery systems, via the Mobile view station, Stand user interface and/or Touch screen module (option).

The differences between the proposed **StentBoost Mobile** and the predicate device *StentBoost rel. 4* do not raise any new questions regarding safety or

effectiveness. Based on the information provided in this 510(k) submission, the proposed **StentBoost Mobile** is considered substantially equivalent to the currently marketed predicate *StentBoost rel. 4* in terms of fundamental scientific technology.

Performance Data: The non-clinical performance testing has been performed on **StentBoost Mobile** 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.

Software verification testing of the functional requirements as well as performance 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 **StentBoost Mobile** conforms to the intended use, claims, user needs, effectiveness of safety measures and instructions for use. All these tests were used to support substantial equivalence of the subject device and demonstrate that **StentBoost Mobile**:

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

Therefore, **StentBoost Mobile** is substantially equivalent to the predicate device *StentBoost Rel. 4* in terms of safety and effectiveness.

Clinical Performance Data:

The proposed **StentBoost Mobile** did not require clinical study since substantial equivalence to the currently marketed and predicate device *StentBoost* was demonstrated with the following attributes:

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

Conclusion:

StentBoost Mobile is substantially equivalent to the currently marketed predicate device *StentBoost Rel. 4* (K132305) in terms of indications for use, fundamental scientific technology (image processing algorithm), 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 **StentBoost Mobile** 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.