Philips Medical Systems Nederland B.V.
Owen Callaghan
Regulatory Affairs Manager
Veenpluis 4-6
5684 PC Best, The Netherlands

Re: K181311
   Trade/Device Name: Philips Hemodynamic Application R1.0
   Regulation Number: 21 CFR 870.2300
   Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
   Regulatory Class: Class II
   Product Code: MWI
   Dated: August 6, 2018
   Received: August 8, 2018

Dear Owen Callaghan:

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,

Stephen C. Browning -S5

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Philips Hemodynamic Application is intended for use by professional healthcare providers for physiologic/hemodynamic monitoring, medical data processing and analytical assessment.

The software may be used to display and/or analyze surface Electrocardiogram (ECG), Respiration, Invasive Blood Pressure (IBP), Pulse Oximetry (SpO2), End Tidal CO2 (ETCO2), Fractional Flow Reserve (FFR), Instant Wave-Free Ratio (iFR), Non-Invasive Blood Pressure (NIBP), surface body Temperature and thermal Cardiac Output.

The software is intended for use with other devices, such as physiological monitoring systems, information management systems, image acquisition and other medical devices.

Use of the software in combination with physiological monitoring system is not intended to be used where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The software in combination with an information management system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet.

The software is indicated for use in the following areas: (interventional) cardiology, electrophysiology and radiology.

The Philips Hemodynamic Application is indicated for use for all human patients of all ages.
510(k) Summary

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

Date Prepared: May 14, 2018

Manufacturer: Philips Medical Systems Nederland B.V.
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Device: Trade Name: Philips Hemodynamic Application R1.0
Classification Name: Cardiac monitor (including cardiotachometer and rate alarm)
Classification Regulation: 21 CFR 870.2300
Classification Panel: Cardiovascular
Device Class: Class II
Primary Product Code: MWI Monitor, Physiological, Patient (without Arrhythmia Detection or alarms)
Secondary Product Code: --

Primary Predicate Device: Trade Name: Xper Flex Cardio Physiomonitoring system
Manufacturer: Witt Biomedical Corporation (a wholly owned subsidiary of Philips Holding USA, Inc.) latterly transferred to Invivo, a division of Philips Medical Systems
510(k) Clearance: K101571 (October 26, 2010)
Classification Name: Cardiac monitor (including cardiotachometer and rate alarm)
Classification Regulation: 21 CFR 870.2300
Classification Panel: Cardiovascular
Device Class: Class II
Device description: **Philips Hemodynamic Application** is a new software medical device that enables invasive investigation of cardiac and vascular disease. It will be offered as an optional accessory to the *Xper Flex Cardio Physiomonitoring System*, (K101571). Currently, the functionality offered by the **Philips Hemodynamic Application** is provided by “Hemodynamic Control Software” of the currently marketed and predicate *Xper Flex Cardio Physiomonitoring System*.

The software connects to the patient monitor (i.e. the *Xper Flex Cardio Physiomonitoring System*) and during the intervention continuously acquires real-time physiological data and alarms. In addition, **Philips Hemodynamic Application** provides the following functionality:

- Visualize and analyze: surface ECG, Respiration rate (RR), Invasive Blood Pressure (IBP), Pulse Oximetry (SpO2), End Tidal CO2 (etCO2), Non-invasive monitoring and recording of Non-Invasive Blood Pressure (NIBP), Body surface temperature (Tskin);
- Provide Hemodynamic calculations: Fractional Flow Reserve (FFR), Instant Wave-Free Ratio (iFR), thermal cardiac output parameters, valve area and valve gradient.

Furthermore, **Philips Hemodynamic Application** also interfaces with Xper Information Management (XperIM) System (K101571) which it can transfer data to for the purpose of data collection/display, processing and patient reporting.
Indications for Use: The **Philips Hemodynamic Application**, provided as an optional accessory to the Philips Xper Flex Cardio Physiomonitoring System, has the following indications for use:

The Philips Hemodynamic Application is intended for use by professional healthcare providers for physiologic/hemodynamic monitoring, medical data processing and analytical assessment.

The software may be used to display and/or analyze surface Electrocardiogram (ECG), Respiration, Invasive Blood Pressure (IBP), Pulse Oximetry (SpO2), End Tidal CO2 (ETCO2), Fractional Flow Reserve (FFR), Instant Wave-Free Ratio (iFR), Non-Invasive Blood Pressure (NIBP), surface body Temperature and thermal Cardiac Output.

The software is intended for use with other devices, such as physiological monitoring systems, information management systems, image acquisition and other medical devices.

Use of the software in combination with physiological monitoring system is not intended to be used where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The software in combination with an information management system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet.

The software is indicated for use in the following areas: (interventional) cardiology, electrophysiology and radiology.

The Philips Hemodynamic Application is indicated for use for all human patients of all ages.

The indications for use statement of the Philips Hemodynamic Application are similar to the indications for use of the currently marketed predicate Xper Flex Cardio Physiomonitoring System (K101571).

Both devices are:
- Indicated for use by professional healthcare providers for physiologic/hemodynamic monitoring, medical data processing and analytical assessment.
- Indicated for use in the following areas: (interventional) cardiology, electrophysiology and radiology.
- Not intended to be used where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.
- Indicated for use for all human patients of all ages.

The Indications for Use of Philips Hemodynamic Application have been further detailed by adding a description of the iFR feature. Addition of this functionality does not raise any new question of safety and effectiveness since Philips Hemodynamic Application still has the same intended use as the predicate, namely for use by professional healthcare providers for complete physiologic/hemodynamic monitoring.

Based on the information provided above, the Philips Hemodynamic Application is considered substantially equivalent to the primary currently...
marketed and predicate device *Xper Flex Cardio Physiomonitoring System* in terms of Indications for Use.

**Technological characteristics:**

**Philips Hemodynamic Application** employs comparable technology as implemented in the Hemodynamic Control Software module which is part of the *Xper Flex Cardio Physiomonitoring System* software. The technical similarities are such that both devices:

- Provide visualization of physiology waveforms and/or values (surface ECG, respiration rate, invasive blood pressure, non-invasive blood pressure, pulse oximetry, end tidal CO2, body surface temperature).
- Provide user interface to display acquired physiological waveforms and values.
- Implement algorithms for hemodynamic calculations: Fractional Flow Reserve (FFR), thermal cardiac output parameters, valve area and valve gradient.
- Allow for the setting of alarm limits (upper/lower) and show visual alarms on the host PC. The **Philips Hemodynamic Application** provides the capability to set limits and visualize alarms, however it still requires the predicate to produce the audible alarm.
- Provides a feature such that samples of the live monitoring can be captured.
- Have X-ray system integration which allows table side operation via the touch screen module.
- Interfaces with the cleared Xper Information Management (XperIM) System (K101571), enabling data to be transferred for the purpose of patient data management.

The **Philips Hemodynamic Application** implements the iFR algorithm for invasive blood pressure measurement (iFR spot and pullback) which is not present in the currently marketed predicate. These measurements are identical to the reference devices *Volcano iFR® Modality* and *Volcano iFR® Scout™*. This extends the existing Fractional Flow Reserve (FFR) functionality which uses hyperemic agent.

This difference and the ones outlined above do not raise any new questions regarding safety and effectiveness. Based on the information provided above, the **Philips Hemodynamic Application** is considered substantially equivalent to the primary currently marketed and predicate device *Xper Flex Cardio Physiomonitoring System* in terms of fundamental scientific technology.
Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on Philips Hemodynamic Application and demonstrates compliance with the following FDA recognized consensus standards and FDA guidance document(s):

- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, 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 (Edition 3, 2016-11). FDA/CDRH recognition number 5-117,
- 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),

Non-clinical software verification testing has been performed to verify that all requirements of the System Requirements Specification, User Interaction Design as well as the identified safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements for Philips Hemodynamic Application have been implemented.
Algorithm verification was performed using calibrated simulator tools that confirmed the algorithm was correctly implemented in the product. Results demonstrated that all executed verification tests were passed.

Software validation testing has been performed to validate that Philips Hemodynamic Application conforms to its intended use, claims and user needs. The validation consisted of the following activities:

- Usability validation was performed with both cardiologists and monitoring nurse/technicians in a simulated use environment in a simulated environment. Philips Hemodynamic Application found to be safe and effective for the intended use, users and use environment;
- In-house simulated use design validation was performed with experienced Clinical Marketing specialists that fulfill the intended user profile. The participants executed validation protocols in the form of a device workflow
to validate user needs, intended use and effectiveness of the safety and security related measures. As part of the validation, the implemented algorithms were evaluated as part of the workflow. 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 **Philips Hemodynamic Application**:
- 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, **Philips Hemodynamic Application** is substantially equivalent to the currently marketed predicate device *Xper Flex Cardio Physiomonitoring System* in terms of safety and effectiveness.

### Summary of Clinical Performance Data:
**Philips Hemodynamic Application** did not require a clinical study since substantial equivalence to the currently marketed predicate device *Xper Flex Cardio Physiomonitoring System* 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 **Philips Hemodynamic Application** 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 *Xper Flex Cardio Physiomonitoring System*.

**Substantial Equivalence Conclusion:** **Philips Hemodynamic Application** is substantially equivalent to the currently marketed predicate device *Xper Flex Cardio Physiomonitoring System* 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 **Philips Hemodynamic Application** 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.