Philips Medizin Systeme Boeblingen GmbH
Michael Asmalsky
Senior Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
Boeblingen, Baden Wuerttemberg D-71034
GERMANY

September 1, 2023

Re: K182637
Trade/Device Name: Philips IntelliVue XDS Software
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, DSH, OUG

Dear Michael Asmalsky:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 26, 2019. Specifically, FDA is updating this SE Letter to remove the secondary product code NSX as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter, please contact Aneesh Deoras, OHT2: Office of Cardiovascular Devices, 240-402-4363, Aneesh.Deoras@fda.hhs.gov.

Sincerely,

Aneesh S. Deoras -S

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 26, 2019

Philips Medizin Systeme Boeblingen GmbH
Michael Asmalsky
Senior Regulatory Affairs Engineer
Hewlett-Packard Str. 2
Boeblingen, 71034 De

Re: K182637
Trade/Device Name: Philips IntelliVue XDS Software
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, DSH, NSX, OUG
Dated: March 19, 2019
Received: March 29, 2019

Dear Michael Asmalsky:

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,

Arielle Drummond -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182637

Device Name
Philips IntelliVue XDS Software Rev.M.1

Indications for Use *(Describe)*

The IntelliVue XDS Software is intended for use as an additional, independent display for viewing screens, generated by specified network-connected Philips patient monitors. The IntelliVue XDS Software alone is not intended for remotely monitoring patients without caregivers in vicinity (unattended patients).

It is indicated for local and remote operation of these Philips patient monitors.
It is indicated for printing reports as generated by these Philips patient monitors.
It is indicated to be used by trained healthcare professionals.

Rx Only: Caution, U.S. Federal Law restricts this device to sale by or on the order of a physician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHILIPS

510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1.) The submitter of this premarket notification is:

Michael Asmalsky
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: ++49 7031 463-1277 Fax: ++49 7031 463-2442
e-mail: michael.asmalsky@philips.com

This summary was prepared on April 25th 2019.

2.) The trade names/proprietary names of the device is:

the Philips IntelliVue XDS Software with software Revision M.1.

The common/usual name is:
for the IntelliVue XDS Software: Information system, bedside
(GMDN 17223)

The Classification names for the IntelliVue XDS Software are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	870.2300, II	**MSX**	System, Network and Communication, Physiological Monitors
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
General Hospital	not classified	NSX	Software, transmission and storage, patient data
General Hospital	§880.6310, I	OUG	Medical Device Data System

3.) The modified Philips IntelliVue XDS Software (SW Rev. M.1) is substantially equivalent to the previously cleared Philips IntelliVue XDS Software marketed pursuant to K161531.

4.) Description of the Devices:
The IntelliVue XDS Software (867019) is a bedside information system. The IntelliVue XDS Software provides network services, printing services, patient monitor remote display services, launch pad services, input device sharing services and XDS database services.

The IntelliVue XDS Software can be connected to one or more specified Philips patient monitors and allows the remote viewing of the patient monitor generated data. Depending on the configuration, the remote operation of the network-connected patient monitor with standard off-the shelf information technology equipment input devices (touch screen, keyboard, and mouse) is also supported.

The IntelliVue XDS software does not modify or alter the data of the Philips specified patient monitor, nor does it generate any data on its own. It is solely displaying the patient monitor generated data. It also displays the current alarm and INOP states for the patient, but does not provide an auditory alarm signal announciation function. The IntelliVue XDS Software is not a primary monitoring or alarming device.

The IntelliVue XDS Software is a software only product. It is intended to be installed on customer supplied compatible off-the shelf information technology equipment that meet the technical requirements as specified by Philips.

The IntelliVue XDS Software can currently be connected to the following compatible patient monitors:

The IntelliVue XDS Software can currently be connected to the following compatible patient monitors:

- Philips IntelliVue patient monitors X2/MP2, MP5, MP5SC, MP60-90,
- Philips IntelliVue patient monitors X3/MX100, MX400, MX 430, MX450, MX500, MX550, MX600, MX700 or MX800
- Philips IntelliVue patient monitor XG50

The subject modification adds the Philips Avalon fetal/maternal monitors FM20, FM30, FM40 and FM50 to the list of specified network-connected Philips patient monitors compatible with the IntelliVue XDS Software.

To support the before described purposes the IntelliVue XDS Software was modified to maintain a consistent numbering scheme. The modified common software revision is Rev.M.1.

Intended Use:

The Intended Use has not changed. The Indications for Use of the subject Philips IntelliVue XDS Software (867019) have been aligned with section IV, D.1 of the FDA Guidance about Evaluating Substantial Equivalence in Premarket Notifications [510(k)] issued on: July 28, 2014. The indications for use have slightly changed as a result of this alignment and of the subject modifications.

The device has the following detailed Intended Use and Indications for Use Statements in its Instructions for Use:

> Philips IntelliVue XDS Software:
>
> The IntelliVue XDS Software is intended for use as an additional, independent display for viewing screens, generated by specified network-connected Philips patient monitors. The IntelliVue XDS Software alone is not intended for remotely monitoring patients without caregivers in vicinity (unattended patients)
>
> It is indicated for local and remote operation of these Philips patient monitors.
> It is indicated for printing reports as generated by these Philips patient monitors.
> It is indicated to be used by trained healthcare professionals.
>
> Rx Only: Caution, U.S. Federal Law restricts this device to sale by or on the order of a physician.

5.) Technological Characteristics:
The modified device has the same technological characteristics as the legally marketed predicate device. It is a software only product intended to be installed on Philips specified standard (of-the-shelf) IT devices. It uses a distributed system architecture and it is suitable for use with the specified Microsoft® Operating System and Databases.

6.) Summary of Verification, Validation and Testing Activities and Conclusion:
Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject modified device with respect to the predicate. Testing involved software testing on integration level (functional testing and regression testing) and software testing on system level (hazard analysis testing and dedicated software performance testing).

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's 2005 Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Testing as required by the hazard analysis was conducted and all specified pass/fail criteria have been met. The test results confirmed the effectiveness of the implemented design risk mitigation measures.

Verification according to the applicable safety and performance standards was conducted as described below:

Standard	**Type**
ANSI/AAMI/IEC 62304:2006	General Standard: Software life cycle processes

Pass/Fail criteria were based on the specifications cleared for the predicate device and all test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue XDS Software (SW Rev.M.1) meets all safety and reliability requirements and performance claims.