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: K161767
Trade/Device Name: Philips IntelliVue Guardian Software Revision C.1
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-ray Tube Display
Regulatory Class: Class II
Product Code: DXJ, DQK, 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 January 27, 2017. 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 27, 2017

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

Re: K161767
Trade/Device Name: Philips Intellivue Guardian Software Revision C.1
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ, NSX, DQK, OUG
Dated: December 20, 2016
Received: December 22, 2016

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. 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,

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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K161767

Device Name

Philips IntelliVue GuardianSoftware, Software Revision C.1

Indications for Use *(Describe)*

The IntelliVue GuardianSoftware is indicated for use by healthcare providers whenever there is a need for generation of a patient record.

The IntelliVue GuardianSoftware is intended for use in the collection, storage and management of data from Philips specified measurements and Philips Patient Monitors that are connected through networks.

Type of Use *(Select one or both, as applicable)*

X 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

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
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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 June 23rd 2016.

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

the Philips IntelliVue GuardianSoftware with software Revision C.1.

The common/usual name is:
for the IntelliVue GuardianSoftware: Clinical Information Management System

The Classification names for the IntelliVue GuardianSoftware are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.2450, II	DXJ	Display, cathode-ray tube, medical
General Hospital	not classified	NSX	Software, transmission and storage, patient data
Cardiovascular Devices	870.1425, II	DQK	Programmable diagnostic computer
General Hospital	§880.6310, I	OUG	Medical Device Data System

3.) The modified Philips IntelliVue GuardianSoftware (SW Rev. C.1) is substantially equivalent to the previously cleared Philips IntelliVue GuardianSoftware marketed pursuant to K151736.

4.) Description of the Devices:
The IntelliVue GuardianSoftware (866009) is a Clinical Information Management System. It collects and manages vital signs data acquired from the IntelliVue Cableless Measurements and IntelliVue Patient Monitors. The IntelliVue GuardianSoftware provides review, reporting, clinical documentation, remote viewing, operating, interfacing, storage, printing and predictive trend analytics, meaning trending, notification, calculations and clinical advisories including EWS deterioration status. The IntelliVue GuardianSoftware 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 GuardianSoftware can currently acquire physiological data from the following compatible measuring devices:

- Philips IntelliVue Measurements CL SpO2 Pod, CL NBP Pod, CL Resp Pod,
- Philips IntelliVue Patient Monitors MX400/XG50, MP5 and MP5SC, and
- Philips SureSigns Patient Monitors VS3/VS4

The subject modification adds the Philips Biosensor and the EarlySense InSight Device as additional optional Philips specified measurements to the list of measuring devices compatible with the IntelliVue GuardianSoftware.

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

Intended Use:

The Intended Use and Indications for Use of the subject Philips IntelliVue GuardianSoftware (866009) has not changed as a result of the device modifications. The device has the following detailed Indications for Use Statements in its Instructions for Use:

Philips IntelliVue GuardianSoftware:

The IntelliVue GuardianSoftware is indicated for use by healthcare providers whenever there is a need for the generation of a patient record.

The IntelliVue GuardianSoftware is intended for use in the collection, storage and management of data from Philips specified Measurements and Philips Patient Monitors that are connected through networks.

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 client server 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 devices with respect to the predicate. Testing involved software functional testing and regression testing on an integration and system level as well as testing from the hazard analysis.

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's 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**
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 GuardianSoftware (SW Rev.C.1) meets all safety and reliability requirements and performance claims.