September 30, 2021

Philips Medizin Systeme Boeblingen GmbH
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212208
Trade/Device Name: Philips IntelliVue GuardianSoftware (Rev. E.0X)
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ, DQK
Dated: September 15, 2021
Received: September 16, 2021

Dear Prithul Bom:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212208

Device Name

Philips IntelliVue GuardianSoftware (Rev. E.0X) (866009)

Indications for Use *(Describe)*

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

The IntelliVue GuardianSoftware is indicated for use in the collection, storage and management of data from Philips specified measurements, Philips Patient Monitors and qualified 3rd party measurements that are connected through networks.

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.

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510(K) SUMMARY

The 510(k) summary was prepared in accordance with the requirements with CFR 807.92.

I. SUBMITTER

DATE PREPARED: 03 May 2021

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II. DEVICE INFORMATION

TRADE NAME: Philips IntelliVue GuardianSoftware (Rev. E.0X)

COMMON NAME: Clinical Information Management System

CLASSIFICATION: Class II, 21 CFR 870.2450

PRODUCT CODE: DXJ: Display, cathode-ray tube, medical

SUB PRODUCT CODE: DQK: Programmable diagnostic computer

III. PREDICATE INFORMATION

PREDICATE DEVICES: Philips IntelliVue Guardian Software, Revision D.0 (K180534)
The predicate device has not been subject to a design related recall.

IV. DEVICE DESCRIPTION

The IntelliVue GuardianSoftware is a stand-alone 'Clinical Information Management System (CIMS)' software application with client-server architecture and designed to be used in professional healthcare facilities (i.e. hospitals, nursing homes) and is intended to be installed on a 'customer-supplied', compatible off-the-shelf (OTS) information technology (IT) equipment.

The IntelliVue GuardianSoftware is a documentation, charting, and decision-support software that is configurable by the hospital to suit the needs of individual clinical units. The device collects data/vital signs from the following Philips compatible patient monitor/measuring devices.

Using the collected data, the device provides trending, review, reporting and notification. The 'Guardian Early Warning Score (EWS)' application is integrated into the IntelliVue GuardianSoftware to provide the healthcare professional/provider basic assessment and the ability to recognize early signs of deterioration in patients.

The IntelliVue GuardianSoftware is **not** an alarming device and displays alarms from patient monitors as supplemental information only.

The basis for submission is modification to the legally marketed device (Software Version D.0). These modifications are as follows:

1. Addition of the Philips Patient Monitors, Biosensor BX100 (K192875) and EarlyVue VS30 (K190624), as compatible patient monitor/measuring devices
2. Addition of HL7 import functionality to include 3rd party measurements
3. To maintain consistent numbering scheme. The modified internal software revision is Rev. E.0X, where 'X' denotes sequential revision numbering.

V. INTENDED/INDICATIONS FOR USE

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

The IntelliVue GuardianSoftware is indicated for use in the collection, storage and management of data from Philips specified measurements, Philips Patient Monitors and qualified 3rd party measurements that are connected through networks.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE PERFORMANCE DATA

The modified device has the same intended use, operating principle and technological characteristics as the legally marketed predicate device.

Table 1, below, provides a high-level comparison of the technological characteristics between the Philips IntelliVue GuardianSoftware (Rev. E.0X) and the Philips IntelliVue GuardianSoftware Revision D.0 (K180534)**.**

Table 1: Comparison Table

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
Intended Use	The IntelliVue GuardianSoftware is intended for use by healthcare providers whenever is a need for generation of patient record.	The IntelliVue GuardianSoftware is intended for use by healthcare providers whenever is a need for generation of patient record.	**Substantially Equivalent** IDENTICAL The IntelliVue GuardianSoftware (REV. E.0X) and predicate device is intended for use by healthcare providers. Both devices generate patient records.
Indications for Use	The IntelliVue GuardianSoftware is indicated for use in the collection, storage and management of data from Philips specified measurements, Philips Patient Monitors and **qualified 3rd party measurements** that are connected through networks.	The IntelliVue GuardianSoftware is indicated for use in the collection, storage and management of data with Philips specified measurements and Philips Patient monitors that are connected through networks.	**Substantially Equivalent** Both devices are indicated for use in the collection, storage and management of data. The IntelliVue GuardianSoftware (REV. E.0X) includes "qualified 3rd party measurements" to its indications for use. The difference in indications for use does not affect the substantial equivalence of the subject device relative to the predicate. HL7 testing encompassed the verification and validation testing of 3rd party measurements.

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
			Usability performance demonstrates the device's safety and performance.
TECHNOLOGY AND SPECIFICATIONS			
System Platform	• Client Server Architecture • Compliant with Microsoft® Operating Systems • Installable on customer supplied off the shelf Information Technology Equipment (physical or virtual ITE devices)	• Client Server Architecture • Compliant with Microsoft® Operating Systems • Installable on customer supplied off the shelf Information Technology Equipment (physical or virtual ITE devices)	**Substantially Equivalent** IDENTICAL Both devices utilize identical system platforms.
Operating System(s) and Database	• Windows 8.1 • Windows 10 • Win Server 2012 R2 • Win Server 2016 • **Win Server 2019** • Microsoft SQL Server 2014 • Microsoft SQL Server 2016 • Microsoft SQL Server 2017 • **Android 5.0 or higher (only for mobile client)**	• **Windows 7** • Windows 8.1 • Windows 10 • **Win Server 2008R2** • Win Server 2012 R2 • Win Server 2016 • Microsoft SQL Server 2014 • Microsoft SQL Server 2016 • Microsoft SQL Server 2017 • **Android 4.4 or higher (only for mobile client)**	**Substantially Equivalent** Both devices utilize Windows, Win Servers, Microsoft SQL Server and Android. Differences in the operating systems (OS) are as follows: • Windows As of January 2020, Windows 7 is no longer supported by Microsoft. Therefore, this has been removed as a compatible operating system for the

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
			subject device. • Win Server As of January 2020, Win Server 2008R2 is no longer supported by Microsoft. Win Server 2019 is the newest operating system supported by Microsoft and replaces Win Server 2008R2. To ensure adequate updates, the predicate device's compatible operating system includes Win Server 2019 and the obsoleted Win Server 2008R2 has been removed. • Android As of March 2020, Android 4.4 is no longer supported by Google. Android 5.0 is the newest operating system supported by Google and replacing Android 4.4. The predicate device includes the Android 5.0 and the obsoleted Android 4.4 has been removed.

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
			The addition and removal of operating systems ensures continued support by the operating system (OS) developer. The difference in operating systems (OS) do not affect the substantial equivalence of the subject device relative to the predicate.
Programming Language	• Microsoft® .NET C# • Microsoft® .NET C++ • Java (only for mobile client)	• Microsoft® .NET C# • Microsoft® .NET C++ • Java (only for mobile client)	**Substantially Equivalent** IDENTICAL
Maximum # of Supported	• Patients: 1200 • Servers: 120 • Clients: 240 • SW Clients: 40	• Patients: 1200 • Servers: 120 • Clients: 240 • SW Clients: 40	**Substantially Equivalent** IDENTICAL The maximum number of supported patients, servers, clients and SW clients are identical.
Compatible Devices	• Philips IntelliVue Cableless Measurements CL SpO2 Pod, CL • NBP Pod, Cl Respiration Pod • Philips IntelliVue patient monitors MP5 and MP5SC • Philips IntelliVue MX400/XG50 patient monitors • Philips SureSigns VS3/VS4 patient	• Philips IntelliVue Cableless Measurements CL SpO2 Pod, CL • NBP Pod, Cl Respiration Pod • Philips IntelliVue patient monitors MP5 and MP5SC • Philips IntelliVue	**Substantially Equivalent** Both subject and predicate device are compatible with the following devices: • Philips IntelliVue Cableless Measurements CL SpO2 Pod, CL

Product Features	**Subject Device** **IntelliVue GuardianSoftware (Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware (Model: REV. D.0) 510(k) K180534**	**Substantial Equivalence Determination**
	monitors • **Philips EarlyVue VS30 patient monitor** • Philips Wearable Biosensor • EarlySense Insight Device • **Philips Biosensor BX100**	MX400/XG50 patient monitors • Philips SureSigns VS3/VS4 patient monitors • Philips Wearable Biosensor • EarlySense Insight Device	• NBP Pod, Cl Respiration Pod • Philips IntelliVue patient monitors MP5 and MP5SC • Philips IntelliVue MX400/XG50 patient monitors • Philips SureSigns VS3/VS4 patient monitors • Philips Wearable Biosensor • EarlySense Insight Device The following have been added as compatible devices for the subject device: • Philips EarlyVue VS30 patient monitor (K190624) • Philips Biosensor BX100 (K192875) These compatible devices are new devices released to market. The addition of patient monitoring devices do not affect the substantial equivalence of the subject device relative to the predicate.
SOFTWARE FUNCTIONALITY			
General Overview	• Clinical Documentation • Patient Data Management	• Clinical Documentation • Patient Data Management	**Substantially Equivalent** IDENTICAL

Product Features	**Subject Device** **IntelliVue GuardianSoftware (Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware (Model: REV. D.0) 510(k) K180534**	**Substantial Equivalence Determination**
	• Reporting (SBAR Reports) and Printing • Calculations (Protocol Watch, EWS Scoring) • Clinical decision support / clinical advisories • Storage	• Reporting (SBAR Reports) and Printing • Calculations (Protocol Watch, EWS Scoring) • Clinical decision support / clinical advisories • Storage	
INTERFACES			
System Interfaces (IT Network Requirements)	• Hospital IT (W)LAN infrastructure (customer responsibility) • HL7, ADT, Labs, Paging • **HL7 system interface has been extended to provide HL7 data import**	• Hospital IT (W)LAN infrastructure (customer responsibility) • HL7, ADT, Labs, Paging	**Substantially Equivalent** The subject and predicate device interface with: • Hospital IT (W)LAN infrastructure (customer responsibility) • HL7, ADT, Labs, Paging The difference is that the HL7 system interface (K151736) has been extended to provide HL7 data import. The HL7 data import provides additional interfacing capabilities from third party systems. This change allows for the subject device to expand its compatibility to include third party connection. The addition of HL7 data import

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
			does not affect the substantial equivalence of the subject device relative to the predicate.
Device Interfaces	Internal (part of IntelliVue Guardian Software) interface for connection to measuring devices through hospital LAN	Internal (part of IntelliVue Guardian Software) interface for connection to measuring devices through hospital LAN	**Substantially Equivalent** IDENTICAL
REMOTE CHARACTERISTICS			
Remote Viewing	• Remote viewing of compatible measuring devices by providing an independent display interface • Real-time display of the measuring devices (waves, numerics, alarms, operating functions) • One monitor/patient at a time per client • Connection through networks, by using Infrastructure Service	• Remote viewing of compatible measuring devices by providing an independent display interface • Real-time display of the measuring devices (waves, numerics, alarms, operating functions) • One monitor/patient at a time per client • Connection through networks, by using Infrastructure Service	**Substantially Equivalent** IDENTICAL

Product Features	**Subject Device** **IntelliVue GuardianSoftware** **(Model: REV. E.0X)**	**Predicate Device** **IntelliVue GuardianSoftware** **(Model: REV. D.0)** **510(k) K180534**	**Substantial Equivalence Determination**
Remote Operation	• Remote operation of compatible measuring devices by providing an independent operating user interface • All operations are provided by the host measuring device • Using the end-user supplied PC user interface (i.e. mouse, touchscreen) • Connection through networks, by using XDS Infrastructure Service	• Remote operation of compatible measuring devices by providing an independent operating user interface • All operations are provided by the host measuring device • Using the end-user supplied PC user interface (i.e. mouse, touchscreen) • Connection through networks, by using XDS Infrastructure Service	**Substantially Equivalent** IDENTICAL

VII. PERFORMANCE DATA

The following were not applicable in the determination of substantial equivalence with regards to performance:

- Biocompatibility
- Electrical Safety and Electromagnetic Compatibility (EMC)
- Animal Study
- Clinical Studies

The following performance testing was conducted in the determination of substantial equivalence:

- Performance Testing - Bench
- Software Verification and Validation Testing

Performance Testing - Bench *(Human Factors and Usability)*

This section is only applicable to the Philips IntelliVue GuardianSoftware (E.0X) to:

- Demonstrate human factors (HF)/usability engineering (UE) has been considered and to ensure use-related hazards, and
- Risks have been reduced/removed relevant to HF/Usability.

No mechanical testing was conducted, as this is a software-only device. No bench testing was conducted using *ex vivo, in vitro,* or *in situ* animal or human tissue, or animal carcass or human cadavers.

Testing demonstrated that the Philips IntelliVue GuardianSoftware as safe and effective for the intended use, intended users, and use environment, as the predicate device.

Software Verification and Validation

Software verification and validation testing were conducted and documentation was provided per FDA's Guidance for Industry and FDA Staff "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*". The Philips IntelliVue GuardianSoftware (Rev. E.0X) Level of Concern (LoC) was determined to be Major because the software provides diagnostic information that directly influences the clinician's treatment/therapy decision and could potentially result in serious injury or death to a patient.

Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the subject device with respect to the predicate device. Tests included software testing on an integration level (software functional testing and regression testing) and software testing on a system level (hazard analysis testing and dedicated software performance testing and functional software security testing in system connectivity).

Tests confirmed and support the effectiveness of the implemented design risk mitigation measures; as well as demonstrated that the Philips IntelliVue GuardianSoftware (Rev.E.0X) met all safety and reliability requirements and performance claims.

The following performance testing are not applicable to the subject device as it is a standalone software device:

- Biocompatibility
- Electrical Safety and Electromagnetic Compatibility (EMC)
- Animal Study
- Clinical Studies

VIII. CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench (human factors and usability) testing, software verification and validation testing demonstrate that the Philips IntelliVue GuardianSoftware (Rev. E.0X) does not raise different questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the Philips IntelliVue GuardianSoftware Rev. D.0 predicate device.