September 10, 2018

Philips Medizin Systeme Böeblingen GmbH
Christoph Krause
Senior Regulatory Affairs Manager
Hewlett-Packard-Str.-2
Boeblingen, Baden-Wūrttemberg D-71034
Germany

Re: K173941
Trade/Device Name: Philips IntelliSpace Perinatal Revision K.00
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, DSJ
Dated: July 2, 2018
Received: July 12, 2018

Dear Christoph Krause:

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,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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

K173941

Device Name
Philips IntelliSpace Perinatal Revision K.00

Indications for Use

The Philips IntelliSpace Perinatal Obstetrical Information Management System is indicated for obstetric patients during and after pregnancy, who require monitoring in a healthcare setting.
The Philips IntelliSpace Perinatal system provides:

- Basic and advanced fetal trace alarming for both antepartum and intrapartum patients.
- Central monitoring of maternal alarming.
- Documentation capabilities and data storage.
- Viewing and alarming of patient physiologic data, at remote locations, via the healthcare facility Remote Desktop Session (RDS).
- An interface to launch the Philips IntelliVue XDS Remote Display for remote viewing and operating of compatible patient monitors.

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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"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."

<table>
<tr><th></th><th colspan="2">510(k) Summary for K173941</th></tr>
<tr><td>807.92(a)(1)</td><td>Owner's name

Address, Phone and fax numbers

Name of contact person

Date</td><td>Philips Medizin Systeme

Hewlett-Packard-Str. 2
D-71034 Böblingen
Tel.: ++49 7031 463 1734
Fax.: ++49 7031 2442

Christoph Krause,
e-mail: christoph.krause@philips.com

September 6, 2018</td></tr>
<tr><td>807.92(a)(2)</td><td>Name of the device

Regulation name, Product code</td><td>Proprietary name: Philips IntelliSpace Perinatal Rev. K.00
Common name: Obstetrical Information Management System

<table><tr><th>Device Panel</th><th>Regulation Number, Class</th><th>ProCode</th><th>Regulation Name</th></tr><tr><td>Obstetrical and gynecological devices</td><td>§884.2740, II</td><td>HGM</td><td>Perinatal monitoring system and accessories</td></tr><tr><td>Cardiovascular devices</td><td>§870.1100, II</td><td>DSJ</td><td>Blood pressure alarm</td></tr></table></td></tr>
<tr><td>807.92.(a)(3)</td><td>Identification of legally marketed predicate device</td><td><u>Primary Predicate:</u> K100420, Philips OB TraceVue Obstetrical Information Management System, Software Revision G.00. This predicate has not been subject to a design-related recall.
<u>Reference Device:</u> K141015, IntelliVue Patient Monitors (MX400, MX450, and MX500) with Philips XDS
<u>Reference Device:</u> K082633, IntelliVue Patient Monitor, IntelliVue XDS, Models MP2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90

The predicate and reference devices have not been subject to a design related recall.</td></tr>
<tr><td>807.92(a)(4)</td><td>Description of the device</td><td>Device design and identification
The Philips IntelliSpace Perinatal Rev.K.00 is a patient-oriented, departmental information management system for the obstetrical care environment. It covers OB care in so far as it is relevant for GYN visits, pregnancy, labor, birth and newborn documentation.
It combines surveillance and alarming with comprehensive patient documentation and data storage into one system that covers the continuum of obstetrical care across one or more pregnancies, from the first antepartum visit until delivery and discharge.</td></tr>
</table>

		Environment of use The Philips IntelliSpace Perinatal Obstetrical Information Management System is intended to be used in a healthcare facility environment within the Obstetrical/Gynecological (OB/GYN) department. **Principle of operation** IntelliSpace Perinatal is Software that is installed on a computer-based network system for obstetrical surveillance, alarming, and patient data management. Key options include patient data storage to a network location; an External Server used, for example, to facilitate forms-based patient records and statistical reporting; an optional HL7 link for Admission Discharge Transfer (ADT) messages and ORU (IntelliSpace Perinatal notes) messages; and an optional access via RDS. **Key performance specifications/device characteristics** The Philips IntelliSpace Perinatal Obstetrical Information Management System can be deployed as standalone or network based server client installations. 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. <u>Operating System:</u> • Servers – Windows Server 2012 R2 • Clients – Windows 10 LTSB 2016 <u>HL7:</u> • Compliance with ANSI Health Level 7 (HL7) specification 2.5 <u>System Scalability:</u> • Fetal monitors per system (maximum): 250 • Client sessions per system (maximum): 300
807.92(a)(5)	Indications for Use	**Indications for Use for the subject device** The Philips IntelliSpace Perinatal Obstetrical Information Management System is indicated for obstetric patients during and after pregnancy, who require monitoring in a healthcare setting. The Philips IntelliSpace Perinatal system provides: • Basic and advanced fetal trace alarming for both antepartum and intrapartum patients. • Central monitoring of maternal alarming. • Documentation capabilities and data storage. • Viewing and alarming of patient physiologic data, at remote locations, via the healthcare facility Remote Desktop Session (RDS). • An interface to launch the Philips IntelliVue XDS Remote Display for remote viewing and operating of compatible patient monitors. **Indications for Use for the predicate device** The Philips OB TraceVue Obstetrical Information Management System is indicated for obstetric patients during and after pregnancy, who require monitoring in a healthcare setting. The Philips OB TraceVue provides: • Basic and advanced fetal trace alarming for both antepartum and intrapartum patients. • Central monitoring of maternal alarming.

		• Documentation capabilities and data storage. • Viewing and alarming of patient physiologic data, at remote locations, via the healthcare facility web access (intranet/internet). The Indications for Use for the subject device Philips IntelliSpace Perinatal Obstetrical Information Management System rev.K.00 is the same as for the predicate device Philips IntelliSpace Perinatal Obstetrical Information Management System rev.G except for • the final bullet point, which also includes remote viewing and operating of patient monitors enabled by launching XDS from within Philips IntelliSpace Perinatal. • editorial changes of the product name and the terminology of the manufacturer of RDS technology Microsoft Corporation. The subject and predicate device have the same intended use.
807.92(a)(6)	Technological similarities and differences to the Predicate Device	The fundamental scientific technology employed in the operation of the Philips IntelliSpace Perinatal Obstetrical Information Management System software revision Rev.K.00 has not changed from that of the predicate devices. The device has been modified in order to support the new feature of launching XDS Remote Display application. **Modifications** The modifications of the Philips IntelliSpace Perinatal Obstetrical Information Management System, software revision Rev.K.00 are software modifications only and cover: • The launch of Philips IntelliVue XDS Application in order to allow the user to remotely access IntelliVue Patient monitors by using XDS remote display. • The web TS client resolution has been adopted to standard mobile device screens • Electronic chalkboards have more configurable columns • Additional options for documentation and reporting are provided (more print outs, statistics profiles, default reports, storage options etc.) • HL7-based Interfacing with automated inbound to hospital ADT system • Windows Server have been updated to Windows 7/10/Server2012) • Addition of more supported HL7-IHE profiles • Introduction of roles and permission based patient data access control • Adjustment of alarm sound pressure levels • System Scalability adjusted to o Fetal monitors per system (maximum): 250 o Client sessions per system (maximum): 300 All other measurements parameters that contain signal acquisition and/or physiological algorithms are unchanged in this Premarket Notification. These differences in technological characteristics do not raise different questions of safety and effectiveness.
807.92(b)(1)	Brief Description Nonclinical Data	The modified IntelliSpace Perinatal Software rev.K.00 has been subject to the following nonclinical V&V activities: • Safety and Performance testing was done according to ANSI/AAMI/IEC 62304:2006.

		• Tests as required by Hazard Analysis. All specified pass/fail criteria have been met. Test results confirmed the effectiveness of implemented risk mitigation measures.
		• Functional tests of the modified software including the newly added feature of launching the XDS Remote Display feature, based on
		  • General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
		  • Guidance for FDA Reviewers and Industry, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005. Testing was conducted for software categorized as having a "MAJOR" level of concern.
		The conducted tests demonstrate that start-up parameters provided by the modified IntelliSpace Perinatal software are correctly handed over to the XDS software and that the compatible IntelliVue patient monitors can be correctly operated via the XDS software.
		
		All specified pass/fail criteria have been met.

807.92.(b)(2)	Brief Description Clinical Data	The similarities and differences between the subject device and the predicate device (see section 5), in particular the modifications to the predicate device, were determined not to have a significant impact on the device's performance, the clinical performance, and the actual use scenarios. Therefore, a clinical study was not needed for the changes provided with the Philips IntelliSpace Perinatal Obstetrical Information Management System software revision Rev.K.00.
807.92(b)(3)	Conclusions drawn from the nonclinical & clinical tests (discussed above)	The successful V&V tests demonstrate that the device is as safe and effective and is therefore substantially equivalent to the legally marketed Philips OB TraceVue Obstetrical Information Management System Rev. G.00 (K100420).