K100420
Page 1 of 3

5.0 510(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.

The submitter of this premarket notification is:

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

JUL 23 2010

Tel: +49 7031 463-1277 Fax: +49 7031 463-2442
Email: michael.asmalsky@philips.com

This summary was prepared on January 30th, 2010.

5.1 Device Names

The names of the devices is the **Philips OB TraceVue Obstetrical Information Management System software revision Rev.G.00**. Classification names are as follows.

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740, II	HGM	Perinatal monitoring system and accessories
Circulatory System Devices	§870.1100, II	DSJ	Alarm, Blood Pressure

5.2 Subject devices

The subject device Philips OB TraceVue Obstetrical Information Management System, software revision Rev.G.00 is substantially equivalent to the previously cleared Philips OB TraceVue Obstetrical Information Management System Rev. F.00 (K081203, May 28th 2008) and the Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 K071800 (September 27th 2007) and the Philips M3290A Intellivue Information Center Software Release E.1 K031403 (May 30th 2003) and Software release G.00 K050742 (April 05th 2005)

5.3 Modifications

The modifications of the Philips OB TraceVue Obstetrical Information Management System, software revision Rev.G.00 are only software modifications and cover:

- the capability for authorized healthcare professionals to configure the generation of alarms from maternal parameters, starting with maternal non-invasive blood pressure.

- The adaptation to settings described in the NICHD April 2008 workshop report on Electronic Fetal Monitoring. This includes a small adaptation in the system setup settings of the CTG module and the generation of contraction alarms within the intrapartum part of the alarming module

- the capability for healthcare professionals to configure the complementary viewing and alarming of patient physiological data at remote locations, using the hospitals web access (hospital intra/internet).

All other measurement parameters that contain signal acquisition and/or physiological algorithms are unchanged in this Premarket Notification.

The before described modifications are reflected in the updated instructions for use and in the updated technical data sheets. The updated instructions for use also contain other minor improvements due to latest findings and suggestions. The current drafts of both documents are attached in Annex A of this submission.

Improvements that are purely data management improvements in the meaning of the Draft Proposed Rules Docket No. 2007N-0484, CDRH 200553 Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, published February 8th, 2008 are not considered in

this notification.

5.4 Intended Use

Details in the intended use of the subject device, as described in the labeling, have changed. The wording has been editorially clarified. The product itself has been modified slightly.

Excluding the added intended use of creating awareness by alarming the user of suspicious maternal parameters, the intended use is the same as previously cleared for the legally marketed predicate device Philips OB TraceVue Obstetrical Information Management System Rev. F.00 (K081203 May 28th 2008)

Intended Use:

The Philips OB TraceVue Obstetrical Information Management System
is intended to acquire, present and store patient information and to document relevant monitor information (surveillance) of patients in the OB/GYN departments of healthcare facilities, as needed by healthcare professionals.

It offers antepartum and intrapartum alarming and optional storage. It helps to monitor and chart the labor of patients.
It can create awareness by alarming the user of suspicious traces and maternal parameters, but leaves the decision about what action to take to the clinician.

Patient-related data can be stored to ensure a complete, permanent record of patient data.

The device is a prescriptive device. US federal law restricts this device to sale by, or on the order of, a physician. Physical patient contact is not intended for the medical purpose of the device.

A table of comparison of the updated and clarified wording and the original wording is provided in section 12 Substantial Equivalence discussion.

5.5 Technological Characteristics

The fundamental scientific technology employed in the operation of the Philips OB TraceVue Obstetrical Information Management System software revision Rev.G.00 has not changed from that of the predicate devices as a result of the modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Michael Asmalsky
Sr. Regulatory Affairs Engineer
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
BOEBLINGEN GERMANY d-71034

JUL 2 6 2010

Re: K100420
Trade/Device Name: Philips OB TraceVue Rev.G.00
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, DSJ
Dated: July 16, 2010
Received: July 21, 2010

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100420

Device Name: Philips OB TraceVue Rev.G.00

Indications for Use

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 (intra/internet).

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100420