MAR 2 3 2006

SECTION 5

510(k) Summary

K060230

DOPPLEX CENTRALE

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Name of Device Dopplex Centrale

Manufactured by Huntleigh Healthcare Ltd.
Diagnostics Products Division
35 Portmanmoor Road,
Cardiff
CF24 5HN
UK

Contact Person Huw Jones

Date of summary 5th December 2005

Classification Name Perinatal monitoring system and accessories
Product code HGM
CFR number 884.2740

Predicate Device Philips OB TraceVue (K970456)
Formerly Hewlett Packard (Agilent) Series 50OB TraceVue

Device Description

The Dopplex Centrale (DCII) monitoring system provides a powerful flexible solution to satisfy current and future central monitoring requirements for perinatal care wards. Various makes of fetal monitor can be linked to Dopplex Centrale which collects data from up to 48 beds in real time. This data is displayed graphically to the user at conveniently sited client workstations. The CTG information is saved using a secure database for subsequent review and patient management. Dopplex Centrale is customisable at manufacturer to cater for disparate needs of particular antenatal clinic or labour ward sites. Dopplex Centrale can be configured to suit the operating protocols of individual customers.

Key Features of Dopplex Centrale

- Only one software release for all installations. Supplementary or custom features offered as additional component modules to the core functionality. Unwanted options are disabled at supply via manufacturer configurable software switches.
- Capable of data exchange with an external HIS via HL7 interface or similar according to customer supplied specifications and acceptance requirements.
- Collection of real-time fetal and vital-signs data from Huntleigh and other supported fetal monitors by third party equipment manufacturers using industry standard data communication protocols.
- Fetal monitor CTG data transmitted over serial port via direct link to Dopplex Centrale or by means of a local area network (wireless and wired IEEE802.11) using external access equipment such as bridges, routers and data concentrators.
- Configurable trace rates and vertical scales
- The real-time data can be viewed anywhere on the DCII network. Single or multiple traces can be viewed. Each trace offers smooth horizontal scrolling, on trace display and annotation of traces, date/time indication.
- Alerts (Bradycardia, Tachycardia, loss of contact, cross-channel twins monitoring verification) are displayed on the CTG trace, in the bed column and as an audible alert. A user can customise the alert settings or the default settings can be used. Colour bands on the graticule indicate the alert settings. These are supplementary to the local alert thresholds on the individual fetal monitors.
- Key clinical indicators are displayed below the chart so that users can view important information specific to a patient. These indicators are selected when the user enters a patient's data.
- A 'chalkboard' option provides an overview of the current status of all beds on the unit. The format of the 'chalkboard' information table is customisable at manufacture or by the system administrator. The default 'chalkboard' fields are "Consultant", "Midwife" and "Comments". The 'chalkboard' display is a live overview of the current status of the unit and its data is not saved
- A labour suite administrative option provides a customisable table which is primarily intended to provide an on-call duty rota with contact details, for key obstetric staff and other specialists who may need to be consulted in an emergency.
- A partogram option allows the progress of labour to be viewed as a clinical chart for individual patients. Typically, data is entered into the partogram chart every 15, 30 or 60 minutes. Partogram layout and content varies widely. Dopplex Centrale is able to customise the chart style according to local requirements.

- Beds can be grouped together under generic categories such as 'labour ward' or 'day centre' to permit optimal flexibility in organising the layout of the system.
- All CTG traces and partogram charts can be retrieved from the database for reviewing.
- Able to accept off line CTG files via a dial-up modem connection to a Fetal Assist portable fetal monitor working remotely in the community. Dopplex Centrale only supports a modem connection with this Huntleigh product using a pre-defined and company confidential data format. Remotely downloaded Fetal Assist files are stored in the database and accessed for review as per on-line recordings.
- The patient details dataset is fully customisable at manufacture according to user requirement specification.
- Each CTG can have a set of trace notes attached to it. These notes are fully customisable at manufacture according to user requirement specification.
- Dopplex Centrale II can print patient reports, which can be configured by the user or system administrator. The reports can contain any data available in the database.
- Dopplex Centrale II can limit the information displayed to the user so that if a client is running in an insecure environment the data displayed can be set to be non-patient specific.
- Dopplex Centrale II provides on-line help and a reference library.
- Dopplex Centrale II provides an audit log.
- Dopplex Centrale II provides full patient backup by means of an automated database archive and backup service. The data can be archived to removable media.
- Dopplex Centrale II provides user authentication and authorisation for some or all of the actions within the system.
- If Centrale II loses contact with a Fetal Assist monitor for a length of time (user defined) and then re-establishes contact with the assist or monitor, a command is sent out asking for any buffered data which may be held by the monitor concerned. If historical data is available it will be sent through in bulk form so that the gaps in the trace can be filled in. The amount of historical data sent will not affect the transmission of the real-time data.

Summary of Safety and Effectiveness

Dopplex Centrale (DCII) replicates the essential functions of the Phillips OB TraceVue system for applications requiring centralised perinatal monitoring of CTG devices.

Dopplex Centrale permits easy-to-use patient surveillance within a hospital environment. It is modular in nature and can be tailored to the working practices of individual institutions through the use of various feature options that are configured by the manufacturer.

The modular nature of its implementation allows Dopplex Centrale complete flexibility in terms of deployment architecture. Again, under manufacturer control subjugate to agreement of customer requirements. It is possible to build a stand-alone solution consisting of a single computer or a fully networked system using a central server and up to 50 remote client machines. Dopplex Centrale provides Obstetric and Gynecology departments with an electronic alternative to conventional perinatal paper charts and records. Dopplex Centrale collects the real-time data from up to 48 fetal monitors and saves this information within a managed database.

The CTG data as received from multiple bed sources can be viewed on screen in an effective and comprehensible manner. Dopplex Centrale interchangeably supports data communication protocols for a variety of fetal monitor models including the Huntleigh BD4000 and the Phillips Series 50 range.

The hardware for this system is off the shelf PCs and servers which meet the required performance specification. The central server will always be supplied to the end user as a pre-configured computer by the manufacturer.

Substantial equivalence between Dopplex Centrale and the Phillps OB TraceVue product has been determined through a comprehensive review of the features of the latter as defined within its product labelling and marketing information. This indicated that Dopplex Centrale is substantially equivalent to the legally marketed predicate device with regards to safety effectiveness and intended use.

The safety of the computer platform host machines is shown by compliance with the relevant standards for ITE devices such as UL1950, IEC950 or EN60950. The electrical safety requirements for the holistic system have been established by review of EN 60601-1-1. Software safety is demonstrated by conformance with the Risk Assessment requirements BSEN60601-1-4 and extensive validation procedures prior to release to end users.

The intended use of this device is the same as the intended use for many other products which are already placed on the market. These devices, as well as the predicate OB TraceVue, provide similar information as is furnished by Dopplex Centrale. This clinical information can be interpreted by medical professionals working within the Obstetric and Gynecology field. Therefore, all aspects of Dopplex Centrale have predicates in other devices which are already well accepted within the clinical community.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Huntleigh Healthcare
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K060230
Trade/Device Name: Dopplex Centrale DCII
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: March 6, 2006
Received: March 8, 2006

Dear Mr. Preiss:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): K060230

Device Name: Dopplex Centrale DC II

Indications for Use:

Dopplex Centrale (DCII) is a software package that collects and manages real-time data from a maximum of 48 individual fetal monitors which are connected to a central server by means communication links.

Dopplex Centrale is indicated for use in healthcare facilities by healthcare professionals whenever there is a need for comprehensive and centralised obstetrical surveillance of those maternal patients who are being monitored by otherwise autonomous CTG devices. Fetal heart rate information can be concurrently viewed on up to 50 conveniently sited computers including a central station, patient bedsides, nurses' lounges and physicians' offices.

Dopplex Centrale provides an easy to use means of patient surveillance within a perinatal environment within a hospital. A Dopplex Centrale system is specified, supplied, commissioned and maintained exclusively by the manufacturer, Huntleigh Healthcare, or its appointed agents. It provides storage and archiving of FHR traces together with the associated patient details.

The specific medical indications for the use of this device is :

- This device is a prescription device
- This device is not intended to contact the patient
- This device is used continuously in Obstetrical Departments
- Basic fetal trace alerting for antepartum and intrapartum applications
- The physiological purpose is indirect. The device is intended to gather and store fetal and maternal information provided by the attached fetal monitors which constitute the primary care sources.

Prescription Use YES (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** NO (21 CFR 801 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 K060230