PHILIPS

K111083 510(k) Summary
Avalon Fetal/Maternal Monitor FM20/30, FM40/50, Release G.0

Submitters Name:

AUG 17 2011

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Date of Summary:

This summary was prepared on July 11th, 2011.

Trade Name of the Device:

Philips Fetal/Maternal Monitor
Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A), FM50 (M2705A)
with software revision G.02.xx ("G.0" release)

Common Name:

Fetal monitor

Classification:

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740, II	HGM	Perinatal monitoring system and accessories
Circulatory System Devices	§870.2780, II	JOM	Plethysmograph

Predicate Device:s

Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40, and FM50
with software revision F.01.xx (K102958)
Philips IntelliVue Patient Monitors MP5 (K071426)
Philips IntelliVue Patient Monitors MP2/X2 (K072070)
Philips OB TraceVue Obstetrical Information Management System Rev. G.00
K100420 (July 26th 2010)

Device Description:

The legally marketed Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40, and FM50 offer monitoring of fetal and maternal heart rates, uterine activity, maternal ECG wave, maternal non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) with pulse rate, during antepartum testing and labor and delivery.

The Avalon Fetal/Maternal Monitor FM20 provides the following external measurement parameters:

- Up to three Fetal Heart Rates (FHR) via ultrasound (US)
- Fetal Movement Profile
- Uterine activity via external Toco
- Maternal pulse rate
- Maternal Heart Rate via maternal ECG
- Non-invasive blood pressure (NIBP)
- Pulse oximetry (maternal SpO_2)

The Avalon Fetal/Maternal Monitor FM30 shares all the features and capabilities of the Avalon FM20. In addition, the Avalon FM30 provides the following external and internal measurement parameters:

- One Fetal Heart Rate and one fetal DECG wave via direct ECG (DECG) *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG) wave

*) Note: maximum three fetal heart rates can be monitored.

The Avalon Fetal/Maternal Monitor FM40 provides the following external measurement parameters:

- Up to three Fetal Heart Rates (FHR) via ultrasound (US)
- Fetal Movement Profile
- Uterine activity via external Toco
- Maternal Pulse Rate
- Maternal Heart Rate via maternal ECG
- Non-invasive blood pressure (NIBP).
- Pulse oximetry (maternal SpO_2)

The Avalon Fetal/Maternal Monitor FM50 shares all the features and capabilities of the Avalon FM40. In addition, the Avalon FM50 provides the following external and internal measurement parameters:

- One Fetal Heart Rate and one fetal DECG wave via direct ECG (DECG) *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG) wave

*) Note: maximum three fetal heart rates can be monitored.

Device Modifications

The device modifications of the subject Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40, and FM50 include the following changes:

- Operation of the models FM20 (M2702A) and FM30 (M2703A) with an internal rechargeable power source (optional) to support fetal/maternal monitoring during transport within healthcare facilities. This additional use case is a minor extension of the intended use.

- Modification of the existing Toco transducer M2734A to include maternal pulse measurement, using plethysmography at an alternative body location (abdomen). The modified transducer is labeled M2734B 'Toco MP'.

- Automated antepartum fetal/maternal trace interpretation and printout of the resulting non-stress test (NST) report.

- The new software G.02.xx, which is a modification of the software F.01.xx (cleared with K102958) to support the before listed modifications / additions.

- Additionally, the option to equip the Avalon Fetal/Maternal Monitors with maternal SpO_2 measurement is enabled now also for the model FM20 (M2702A).

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

Indications for Use:

Avalon Fetal/Maternal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM40:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal/Maternal Monitor FM50:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Technological Characteristics:

The fundamental scientific technology employed in the operation of the Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40 and FM50 has not changed from that of the predicate devices as a result of the modification.

Non-clinical Testing:

Verification and validation activities established the performance, functionality, and reliability characteristics of the modified devices with respect to the predicates. Testing involved system level and regression tests as well as testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. Some tests included the use of previously recorded patient raw signals and traces. The bench tests included:

- Cross Channel Verification (CCV) testing including maternal pulse from the M2734B Toco MP transducer as a signal source
- M2734B Toco MP maternal pulse rate accuracy over the full range
- Comparative test of antepartum fetal/maternal trace interpretation and NST report against the implementation in OB TraceVue G.00 (K100420)
- Testing of generic hazards as indicated by the Risk management summary
- Testing of battery-related hazards for the FM20/FM30 as indicated by the Risk management summary
- Interface testing to the OB TraceVue system including date/time and patient identification - Testing of the alarms functionality
- Regression testing for the Toco measurement and for the software G.02.xx
- Testing of the additional minor enhancements introduced with software G.02.xx
- Product Safety and Electromagnetic Compatibility according to IEC 60601-1+A1+A2 and IEC 60601-1-2+A1.

Clinical Testing:

For the clinical validation of the M2734B 'Toco MP' transducer a clinical study has been performed. The patient population was covering a variety of body mass indices (BMI) and skin colors. The maternal pulse rate obtained from the Toco MP transducer has been recorded together with the ECG derived maternal heart rate (MECG) and subsequently compared and evaluated.

Conclusion:

Non-clinical and clinical verification and validation results demonstrate that the Avalon fetal/maternal monitors with software G.02.xx are as safe, as effective, and perform as well or better as the predicate devices with software F.01.xx. The modified devices do not introduce new questions concerning the safety or effectiveness and are, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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GERMANY

AUG 17 2011

Re: K111083
Trade/Device Name: Philips Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A) and FM50 (M2705A)
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, HGL
Dated: July 11, 2011
Received: July 13, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111083

Device Name: Philips Avalon FM20(M2702A), FM30(M2703A), FM40(M2704A) and FM50(M2705A).

Indications for Use:

Avalon Fetal/Maternal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM40:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal/Maternal Monitor FM50:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Prescription Use __Yes____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111083