MAR 18 2011

8.0 510(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:
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This summary was prepared on March 18th, 2011

8.1 Indications for Use

The indications for use of the subject devices has not changed.

Indications for Use:

Avalon Fetal 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, 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 and in private households.

Avalon Fetal 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 and in private households.

Avalon Fetal 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 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.

8.2 Device Names

The names of the devices are the Philips Avalon Fetal Monitors FM20 (M2702A), FM30 (M2703A),FM40 (M2704A) and FM50 (M2705A).

8.3 Device Description

The legally marketed devices Philips Avalon Fetal/Maternal Monitors FM20, FM30, FM40 and FM50 offer monitoring of fetal and maternal heart rates, uterine activity, maternal ECG, maternal non-invasive blood pressure (NIBP) and oxygen saturation (Sp02) 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 (MHR) via maternal ECG
- Non-invasive blood pressure (NIBP)

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

- Single Fetal Heart Rate via direct ECG (DECG) *)
- Twin Fetal Heart Rates via direct ECG (DECG) and/or ultrasound *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG)
- Pulse oximetry (maternal Sp02).

*) Note: maximum three FHR's 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 (MHR) via maternal ECG
- Non-invasive blood pressure (NIBP).
- Pulse oximetry (maternal Sp02).

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

- Single Fetal Heart Rate via direct ECG (DECG) *)
- Twin Fetal Heart Rates via direct ECG (DECG) and/or ultrasound *)
- Uterine activity via intrauterine pressure (IUP)
- Maternal ECG (MECG)

*) Note: maximum three FHR's can be monitored.

8.4 Device Classification

The Philips Avalon Fetal Monitors FM20 (M2702A), FM30(M2703A), FM40(M2704A) and FM50(M2705A) and where applicable including their accessories are classified under ProCcode HGM, classification 884.2740, Perinatal monitoring system and their accessories.

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740, II	HGM	Perinatal monitoring system and accessories

8.5 Subject devices

The subject devices Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 are substantially equivalent to previously cleared Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 marketed pursuant to K071800 and K092028.

8.6 Modifications

The modification of the Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 only provides an improved ultrasound performance algorithm of the released ultrasound transducers and TMIF interface cables to be used with the Philips Avalon Fetal monitors FM20, FM30, FM40 and FM50.
The software changes were made to address problems with halving and doubling of the fetal heart rate and mistaken display of maternal heart rate for fetal heart rate.

8.7 Technological Characteristics

The subject devices Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 have the same characteristics as the legally marketed predicate devices Avalon Fetal Monitors FM20, FM30, FM40 and FM50.

8.8 Verification and Validation

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. 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 traces.

The results demonstrate that the Philips Avalon Fetal Monitors meet all reliability requirements and performance claims.

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
Regulatory Affairs Engineer
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71034 BOBLINGEN
GERMANY

MAR 18 2011

Re: K102958
Trade Name: Avalon Fetal/Maternal Monitors (FM20, FM30, FM40, & FM50)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: February 21, 2011
Received: March 3, 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.

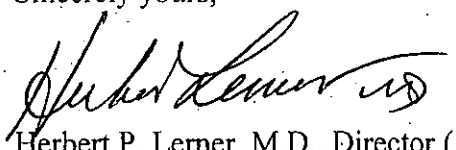
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K102958

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

Indications for Use:

Avalon Fetal 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, 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 and in private households.

Avalon Fetal 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 and in private households.

Avalon Fetal 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 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)

(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, Gastro-Renal, and Urological Devices
510(k) Number K102958