K052795

DEC 30 2005

# SECTION 8.0

# 510(k) SUMMARY

**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.

1. The submitter of this premarket notification is:

Markus Stacha
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This summary was prepared on **September 30, 2005.**

2. The name of the devices is the Philips Avalon Fetal Monitors FM20 and FM30. Classification names are as follows:

| Device Panel | Classification | ProCode | Description |
|---|---|---|---|
| Obstetrical and Gynecological Monitoring Devices | §884.2660, II | MAA<br>HEL<br>HEK<br>KNG | Fetal ultrasonic monitor and accessories |
| | §884.2675, II | HGP | Fetal scalp circular (spiral) electrode and applicator |
| | §884.2700, II | HGS<br>KXO<br>HFO<br>HFN | Intrauterine pressure monitor and accessories |
| | §884.2720, II | HFM | External uterine contraction monitor and accessories |
| | §884.2740, II | HGM | Perinatal monitoring system and accessories |
| | §884.2960, II | HGL | Obstetric ultrasonic transducer and accessories |
| Circulatory System Devices | §870.1100, II | DSJ | Alarm, Blood Pressure |
| | §870.1110, II | DSK | Computer, Blood Pressure |
| | §870.1130, II | DXN | System, Measurement, Blood-Pressure, Non-Invasive |
| | §870.2060, II | DRQ | Amplifier and Signal Conditioner, Transducer Signal |
| | §870.2300, II | DRT | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) |
| | §870.2340, II | DPS | Electrocardiograph |
| | §870.2600, I | DRJ | System, Signal Isolation |
| | §870.2700, II | DQA | Oximeter |
| | §870.2810, I | DSF | Recorder, Paper Chart |
| | §870.2900, I | DSA | Cable, Transducer and Electrode, incl. Patient Connector |

3. The modified devices Avalon Fetal Monitors FM20 and FM30 are substantially equivalent to previously cleared Philips devices marketed pursuant to K954351, K041235, K042845, K051106,

K051366, K030973, K033715, K032979, K042306, K970456, and Clinical Innovations devices marketed pursuant to K954955.

4. The subject devices Philips Avalon Fetal Monitors FM20 and FM30 are modification of the legally marketed Philips Series 50XM (M1350B) Fetal/Maternal Monitor (K954351) and offer monitoring of fetal and maternal heart rates, uterine activity, maternal ECG, maternal non-invasive blood pressure (NIBP) and oxygen saturation (Sp02) during antepartum testing and labor and delivery.

5. The modified devices Philips Avalon Fetal Monitors FM20 and FM30 have the same intended use as the legally marketed predicate device Philips Series 50XM (M1350B) Fetal/Maternal Monitor.
   The Philips Avalon Fetal Monitors FM20 and FM30 are intended for non-invasive and invasive monitoring of the physiological parameters of pregnant women during antepartum testing and labor and delivery.
   The Avalon FM20 and FM30 are intended for monitoring fetal and maternal heart rates, uterine activity, maternal non-invasive blood pressure (NIBP) and oxygen saturation (SpO2). The Avalon FM20 and FM30 are intended for generating alarms, for displaying, storing and recording patient data and related waves. The Avalon FM20 and FM30 are intended for use by trained health care professionals in labor and delivery rooms and in antepartum testing areas. They are not intended for use in intensive care units, operating rooms or for use outside the health care facilities.

6. The modified devices Philips Avalon Fetal Monitors FM20 and FM30 have the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicates. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the Philips Avalon Fetal Monitors FM20 and FM30 meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Markus Stacha
Sr. Regulatory Affairs Engineer
Cardiac and Monitoring Systems
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard Str. 2
71034 Böblingen
GERMANY

DEC 3 0 2005

Re: K052795
Trade/Device Name: Avalon Fetal Monitors FM20 and FM30
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Product Code: HGM
Regulation Number: 21 CFR §870.1130
Regulation Name: Noninvasive blood pressure measurement system
Product Code: DXN
Regulatory Class: II
Dated: November 30, 2005
Received: December 2, 2005

Dear Mr. Stacha:

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): K052795

Device Name: Philips Avalon Fetal Monitors FM20 and FM30.

**Indications for Use:**

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 rate in labor and delivery rooms and in antepartum testing areas.

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 rate 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, Abdominal, and Radiological Devices
510(k) Number K052795