AUG 24 2006 K062137

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

Tel: ++49 7031 463-2840 Fax: ++49 7031 463-2442
Email: markus.stacha@philips.com

This summary was prepared on July 21, 2006.

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 HEL HEK KNG	Fetal ultrasonic monitor and accessories
	§884.2675, II	HGP	Fetal scalp circular (spiral) electrode and applicator
	§884.2700, II	HGS KXO HFO 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 Philips Avalon Fetal Monitors FM20 and FM30 are substantially equivalent to previously cleared

Philips Avalon Fetal Monitors FM20 and FM30 marketed pursuant to K052795.

4. The modification of the Philips Avalon Fetal Monitors FM20 and FM30 introduces the capability of monitoring fetal heart rates of triplets.

5. The modified devices Philips Avalon Fetal Monitors FM20 and FM30 have the same intended use as the legally marketed predicate device Philips Avalon Fetal Monitors FM20 and FM30. 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 maternal 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 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 Avalon Fetal Monitors FM20 and FM30.

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 performance tests, regression tests, and testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices 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

AUG 24 2006

Mr. Markus Stacha
Senior Regulatory Affairs Engineer
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str. 1
71034 Böblingen
GERMANY

Re: K062137
Trade/Device Name: Philips Avalon Fetal Monitors FM20 and FM30
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II
Product Code: HGM and DXN
Dated: July 21, 2006
Received: July 26, 2006

Dear Mr. Stacha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following ultrasound transducer intended for use with the Philips Avalon Fetal Monitors FM20 and FM30, as described in your premarket notification:

Transducer Model Number

M2736A, 1 MHz Ultrasound Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Glenn Bell at (301) 594-1180.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K062137

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 rates of single fetuses, twins, and triplets 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 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)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062137