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510(k) Summary
(As required by 21 C.F.R. §807.92)

FEB 2 4 2003

Submitted by:

Markus Stacha
Philips Medizin Systeme Boeblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Str.2
71034 Boeblingen
Germany

Date of Summary: November 22, 2002

Device Name: Philips Avalon CTS Cordless Fetal Transducer System

Common Name: Perinatal Monitoring System

Classification Name

Regulation Number	Classification Name
21 C.F.R §884.2740	Perinatal Monitoring System and Accessories

Predicate Devices: Philips M1310A Fetal Telemetry System-Series 50T (K942887), Philips M1350A Intrapartum Fetal Monitor (K900480), Philips M1350B Perinatal Monitoring System (K954351), Philips M1351A Perinatal Monitoring System (K921957), Philips M1353A Fetal Monitor (K921956) and the Philips M2600A Telemetry Systems (K993516, K980429, and K961165).

Modifications: The modification incorporates the front-end circuitry for each parameter into the transducer, thereby replacing the cable used in the predicate versions by a direct hardware connection. There are no modifications to the device design that affect safety & effectiveness of the Perinatal Monitoring System.

Device Description: The Perinatal Monitoring System operates by measuring, processing, and transmitting standard fetal parameters to any Philips Series 50 fetal monitor using radio transmission technology. A group of three wireless transducers is available to obtain specific fetal data in the antepartum period and during labor and delivery. The transducers are designed to operate while the patient is ambulatory, including activity taking place in a submerged water environment, like bathing and hydrotherapy.

The devices are identified by the following model numbers: System and Base Station M2720A; Toco transducer M2725A (measures uterine activity externally); US transducer M2726A (measures fetal heart rate and fetal movement profile); and the optional ECG/auxiliary transducer M2727A (measures DECG or direct fetal scalp ECG and MECG or maternal ECG).

Intended Use	The intended use of the modified device, as described in its labeling, has not changed from that of the predicate device as a result of the modifications. The Philips M2720A Cordless Fetal Transducer System is indicated for pregnant women from about 22 weeks of gestation on through delivery. It is intended for continuous cordless fetal monitoring in connection with a fetal monitor for resting or ambulating patients, also usable during hydrotherapy, for antepartum testing and labor and delivery (intrapartum). The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of fetal heart rate traces. It is not intended for home use.
Technological characteristics	The Philips Avalon CTS Cordless Fetal Transducer System and accessories have the same technological characteristics as the legally marketed predicate devices.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved environmental, electrical safety, EMC, radio telemetry, biocompatibility and user evaluations for consumer accuracy. Hardware and software verification testing and cable interface verification testing were also conducted. Test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2003

Mr. Markus Stacha
Regulatory Affairs Engineer
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str.2
71034 Böblingen
GERMANY

Re: K023931
Trade/Device Name: M2720A Avalon CTS Cordless Fetal Transducer System
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: November 22, 2002
Received: November 26, 2002

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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 Statement

510(k) Number (if known) K023931

Device Name: The Philips Avalon CTS Cordless Fetal Transducer System (M2720A) and Accessories

Indications for Use: The Philips Avalon CTS Cordless Fetal Transducer System (M2720A) and Accessories is indicated for pregnant women from about 22 weeks of gestation on through delivery. It is intended for continuous cordless fetal monitoring in connection with a fetal monitor for resting or ambulating patients, also usable during hydrotherapy, for antepartum testing and labor and delivery (intrapartum).

The system should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal heart rate monitors and in the interpretation of fetal heart rate traces. It is not intended for home use.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
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