SEP 12 1997

510(k) SUMMARY

FOR HUNTLEIGH HEALTHCARE'S

BABY DOPPLEX® 3000

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Audrey Witko
Compliance Officer
Huntleigh Healthcare
227 Route 33 East
Manalapan, NJ 07726

Phone: (908) 446-2500
Facsimile: (908) 446-1938

Contact Person: same as above

Date Prepared: August 16, 1996

Name of Device and Name/Address of Sponsor

Baby Dopplex® 3000

Huntleigh Healthcare
227 Route 33 East
Manalapan, NJ 07726

Classification Name

Fetal Ultrasonic Monitor and Accessories (21 C.F.R. § 884.2660)

Predicate Device

Hewlett Packard GmbH Model 1351A Fetal Monitor (K921957/A)

Intended Use

Huntleigh Healthcare's Baby Dopplex® 3000 is intended for use as a fetal monitor to perform cardiotocographs. The Baby Dopplex® 3000 is indicated for use in all areas of fetal monitoring except where internal scalp clip monitoring and/or intrauterine pressure measurement is required.

Technological Characteristics and Substantial Equivalence

The Baby Dopplex® 3000 is supplied complete with the following components: the main unit, a single crystal transducer, a contractions or uterine activity transducer, a patient event marker, an integral thermal printer, paper, belts, gel, a detachable power cord, and a user manual. The Baby Dopplex® 3000 includes all the basic functions and features that are internationally recognized as essential requirements for fetal monitors.

With the exception of the power switch, all user controls and displays on the Baby Dopplex® 3000 main unit are arranged on a control panel which is located on the top face of the unit. Controls take the form of membrane type push buttons with tactile feedback. The Baby Dopplex® 3000 utilizes ultrasound energy at 2 MHz to detect the fetus. The power level, frequency, pulse duration and repetition rate are all preset at the manufacturing stage and there are no user controls or adjustments affecting any of these parameters.

The Baby Dopplex® 3000 is substantially equivalent to Hewlett Packard GmbH's Model 1351A Fetal Monitor ("HP 1351A") (K921957/A). The Baby Dopplex® 3000 and the HP 1351A each have the same intended uses and principles of operation. As with its predicate device, the Baby Dopplex® 3000 is designed to transmit and receive ultrasonic energy into and from a pregnant woman, by means of a pseudo-continuous wave (Doppler).

Both the Baby Dopplex® 3000 and its predicate device offer three user selectable chart speeds of 1, 2 or 3 cm/min. Each device provides an LED display for fetal heart rate and uterine activity and each incorporates a computer interface. Based on a U.S. standard of 30 bpm/cm, both units measure fetal heart rate ("FHR") over the range of 50 to 210 bpm. Both devices conform to electrical safety standards UL544 and IEC601-1. As with its predicate device, the Baby Dopplex® 3000 has a PC/ABS alloy plastic casing.

As with its predicate device, the Baby Dopplex® 3000 incorporates the use of a transducer that is held in place on the abdomen by elastic straps. While the HP 1351A utilizes an annular array of crystals operating at 1 MHz, the Baby Dopplex® 3000 utilizes a single crystal with a divergent lens operating at 2 MHz.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 1997

Ms. Audrey Witko
Compliance Manager
Huntleigh Healthcare, Inc.
A Huntleigh Technology Inc. Company
227 Route 33 East
Manalapan, New Jersey 07726

Re: K963711
Baby Dopplex® 3000 Fetal Monitoring Device
Dated: June 13, 1997
Received: June 16, 1997
Regulatory Class: II
21 CFR § 884.2740/Product Code: 85 HGM

Dear Ms. Witko:

We have reviewed your Section 510(k) 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 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.

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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Baby Dopplex® 3000

Indications For Use:

The Baby Dopplex® 3000 is intended for use as a fetal monitor to perform cardiotocographs ("CTG"), i.e., fetal monitoring. The Baby Dopplex® 3000 is indicated for use in all areas of fetal monitoring except where internal scalp clip monitoring and/or intrauterine pressure measurement is required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K963711

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)