K965008 1/2

510(k) Summary

Advanced Medical Systems BirthNet™ II
Perinatal Patient Data Management System

DEC 16 1997

1. Submitter's Name: Advanced Medical Systems, Inc.
925 Sherman Avenue
Hamden, CT 06514
Telephone: (800) 325-2070
Facsimile: (203) 288-9032

2. Name of Device: BirthNet™ II Perinatal Patient Data Management System

Classification: The BirthNet™ II Perinatal Patient Data Management System is classified under Perinatal Monitoring System and Accessories which has been classified as a Class II device, in accordance to 21 CFR 884.2740.

3. Predicate Devices: The AMS BirthNet™ II Perinatal Patient Data Management System is substantial equivalent to the Quantitative Sentinel Perinatal, as described in K960109; and the Air Shield WatchChild as described in K893981.

4. The BirthNet™ II Perinatal Patient Data Management System is a comprehensive on-line, real-time information system to collect, display, and store physiological (e.g. fetal heart rate and uterine activity) data and other pertinent patient medical information. Designed specifically for pregnancy, delivery, and early neonatal care, medical personnel can review the status and management of each patient form any hospital based workstation. The primary function of the BirthNet™ II Perinatal Patient Data Management System is to automatically receive and record physiological monitoring data, and correlate this data with health care practitioner supplied data such as medicinal administrations, and recognized physical and physiological conditions.

The BirthNet™ II Perinatal Patient Data Management System is also designed to interface with all AMS fetal monitors and most all fetal and maternal physiological monitors presently available. Patient information can be archived onto optical disks for long-term storage. Aggregate statistical reports can also be generated.

5. The BirthNet ™ II Perinatal Patient Data Management System is designed for use to capture, display, and manage physiological obstetrical and fetal patient data. It is intended to permit the real-time monitoring of multiple obstetrical and fetal patients simultaneously, and to correlate non-monitored patient data with monitored physiological parameters.

6. The BirthNet ™ II Perinatal Patient Data Management System software is manufactured by conventional CD-ROM replication from an authenticated master image under configuration control. The interface modules are comprised of surface mounted printed circuit boards and manufactured in a conventional manner. The installed software is validated prior to release and functionally tested at installation using validated test software.

7. The BirthNet ™ II Perinatal Patient Data Management System has been subject to extensive safety testing and will be subject to extensive performance testing prior to release. Final testing for the system includes a comprehensive validation of the entire system requirements. Safety tests have been performed to ensure the device complies to all applicable industry and safety standards.

   In conclusion, the BirthNet ™ II Perinatal Patient Data Management System is as safe and effective as the predicate devices and raises no new issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1997

Mr. Anthony Calderoni
Vice President
Advanced Medical System, Inc.
925 Sherman Avenue
Hamden, Connecticut 06514

Re: K965008
BirthNet™ II Perinatal Patient Data Management System
Dated: September 24, 1997
Received: September 29, 1997
Regulatory class: II
21 CFR §884.2740/Product code: 85 HGM

Dear Mr. Calderoni:

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): K965008
Device Name: BirthNet™ II Perinatal Patient Data Management System
Indications for Use:

The BirthNet™ II Perinatal Patient Data Management System is designed for use in the following functions:

a) Collect fetal monitor data for the purpose of central surveillance, local surveillance, review, annotation, and for archiving data for long storage.
b) Report alert conditions generated by the AMS fetal monitors or the AMS computer interface module (CIM).
c) Collect physiological, maternal and fetal data directly from physiological monitors and append such data to the proper patient database table.
d) Feed back selected data items to the AMS fetal monitor for the purpose of printing such data on the fetal monitor strip in real time.
e) Enable manual patient data entry into the system for the purpose of charting.
f) Assemble and display selected data in a summary format of r more efficient review capability by the care giver.
g) Validate data entry when applicable to ensure data integrity.
h) Print pre-formatted reports on individual patients
i) Reproduce fetal monitor records from storage to a printer or an AMS UR10 (stripped down fetal monitor) recorder.
j) Transmit selected items from the database via fax.
k) Enable authorized (password) care giver to access the system remotely.
l) Generate an audit trail for all transactions.
m) Generate statistics reports for quality assurance.
n) Facilitate the generation of a birth certificate by providing pertinent patient data acquired by the system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K965008

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

(Optional Format 1-2-96)