

OCT 7 1998

510(k) Submission

Submitter: Air-Shields Information Systems
Marci L. Goldfinger, Director, Quality Assurance and Regulatory Affairs
330 Jacksonville Road
Hatboro, PA 19040
Phone: 215-675-5200
Fax: 215-675-1859

Date summary was prepared: November 11, 1997

Name(s) of the device: WatchChild™ Obstetrical Patient Data Management System

Identification of predicate device(s) Six predicate devices are identified in the submission. They include:

K893981	Original WatchChild System
Unknown	AMS DASTAR
K970456	OB Trac Vue
K870692	Peritronics 9000C
K960109	Quantitative Sentinel
K903992	Cygnnet Central

Description of the device:

The WatchChild™ Obstetrical Patient Data Management System is a data management system that interfaces with patient monitoring equipment to record, display and/or archive the data. The system is a computer based system that contains software for easy data storage and retrieval of fetal/maternal data. The system is comprised of, in addition to the software, an IBM RISC System/6000, redundant disk drives to assure reproducibility of information, X-terminal graphics workstation, optical disk drive, and laser printer.

510(k) Submission

WatchChild archives all fetal monitor data, maternal hemodynamic and waveform data (NIBP and SaO₂), patient charting, admission forms, examinations, flowsheets, medications, lab results, discharge information, and notes. WatchChild automatically reads NIBP, SaO₂, and heart rate at hospital defined intervals.

Intended Use

The WatchChild™ System is a complete Obstetrical Information Management System which has the ability to record, store, and display data from fetal monitors and maternal vital signs monitors, and manages patient information from the initial Fetal Stress Tests through post delivery discharge. WatchChild organizes clinical data which would normally be provided on paper records or other clinical systems and devices. This system serves as a decision support tool as well as an electronic medical record. This device is intended for use in a hospital/clinical environment.

Comparison of device characteristics to predicate

The WatchChild™ Obstetrical Patient Data Management System is equivalent to the predicate devices identified above. The system has the same capabilities to record, display, archive data collected from fetal monitors and maternal monitors. The features that are common to all of the predicates are features that are contained in the WatchChild system.

Non clinical testing:

The software was tested to verify and validate the software.

Clinical testing:

None required

Conclusion:

Based on the information contained in this notification, it is concluded that the WatchChild™ Obstetrical Patient Data Management System is substantially equivalent to the legally market systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1998

Ms. Marci L. Goldfinger
Director, Quality Assurance and Regulatory Affairs
Hill-Rom® Air-Shields, Inc.
330 Jacksonville Road
Hatboro, PA 19040

Re: K974248
WatchChild™ Obstetrical Patient Data Management System
Dated: July 15, 1998
Received: July 17, 1998
Regulatory Class: II
21 CFR 884.2740/Procode: 85 HGM

Dear Ms. Goldfinger:

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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,

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 **K974248**

To be assigned by FDA

Device Name: WatchChild™ Obstetrical Patient Data Management System

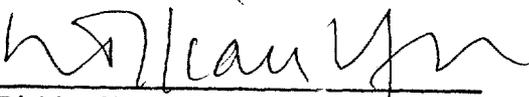
Indications for Use:

The WatchChild™ System is a complete Obstetrical Information Management System which has the ability to record, store, and display data from fetal monitors and maternal vital signs monitors, and manages patient information from the initial Fetal Stress Tests through post delivery discharge. WatchChild organizes clinical data which would normally be provided on paper records or other clinical systems and devices. This system serves as a decision support tool as well as an electronic medical record. This device is intended for use in a hospital/clinical environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

Over-the Counter Use



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974248/S1