



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Dawn M. Reilly, RAC  
Official Correspondent  
Manager, Regulatory Affairs & Quality Assurance  
Hill-Rom Manufacturing, Inc.  
1225 Crescent Green, Suite 200  
CARY NORTH CAROLINA 27518

APR - 9 2008

Re: K080226  
Trade Name: NaviCare® WatchChild™ Obstetrical Data Management System  
Regulation Number: 21 CFR §884.2740  
Regulation Name: Perinatal monitoring system and accessories  
Regulatory Class: II  
Product Code: HGM  
Dated: March 7, 2008  
Received: March 10, 2008

Dear Ms. Reilly:

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 (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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

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.

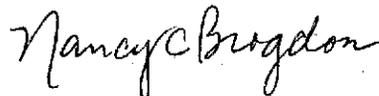
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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>.

Sincerely yours,



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

Enclosure



Hill-Rom Manufacturing  
 1225 Crescent Green, Suite 200  
 Cary, North Carolina 27518

Special 510(k) Submission:  
 NaviCare® WatchChild™

## Attachment A: Indications for Use Statement

510(k) Number:  
 (if known)

K080226

Device Name:

NaviCare® WatchChild™

Indications for Use:

NaviCare® WatchChild™ is indicated for use in a hospital/clinical environment. NaviCare® WatchChild™ is intended to be used as a complete Obstetrical Data Management System, which has the ability to record, store and display data from fetal and maternal vital signs monitors. It manages patient information from the initial prenatal care to post-delivery discharge. NaviCare® WatchChild™ organizes clinical data that would normally be provided on paper records or other clinical systems and devices. This system also serves as a decision support tool and electronic medical record.

Prescription  
 Use X  
 (Per 21 CFR 801. 109)

AND/OR

Over-The-Counter  
 Use \_\_\_\_\_  
 (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K080226