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510(k) SUMMARY

McKesson Information Solutions, LLC's Horizon Perinatal Care Surveillance and Archival System

McKesson Information Solutions, LLC
11000 Westmoor Circle Suite 125
Westminster, CO 80021

Contact Person: Louise Smith, Director Regulatory Assessment & Compliance Operations
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Date Prepared: August 6, 2010

Proprietary / Trade Name: Horizon Perinatal Care Surveillance and Archival System
Common or Usual Name: Perinatal monitoring systems and accessories
Classification Name: Perinatal monitoring system and accessories, 21 C.F.R. § 884.2740
Product code: HGM
Device Class: II
Predicate Device: LMS Medical Systems, Ltd., CALM (K980719)

Intended Use / Indications for Use:

Horizon Perinatal Care Surveillance and Archival System is intended for use as a central monitoring system, providing fetal surveillance and monitoring of multiple obstetrical and fetal patients simultaneously and to correlate pertinent patient observations of physiological parameters.

Horizon Perinatal Care Surveillance and Archival's indications for use are:

- Interfaces with fetal and maternal monitors to provide fetal surveillance, monitoring of labor progress, display and archiving functions
- Allow care givers to electronically document and store patient information on obstetrical patients in a health care facility; and
- Provides remote access to the HPC S&A system.

Technological Characteristics

The Horizon Perinatal Care Surveillance and Archival System consists of the Horizon Perinatal Care Surveillance and Archival software, which runs on standard "off-the-shelf" hardware components (e.g., servers and workstations). Horizon Perinatal Care Surveillance and Archival uses standard 100 Mbps Ethernet networking technology and is coupled to industry standard fetal monitors that are legally marketed under FDA regulations. Each fetal monitor is attached to a networked computer. Horizon Perinatal Care Surveillance and Archival is able to interface with other pertinent hospital information systems.

Performance Data

Verification and validation testing was performed on Horizon Perinatal Care Surveillance and Archival to ensure it met all specifications. The system was further validated to ensure that it performs as intended. In all instances, Horizon Perinatal Care Surveillance and Archival System functioned as intended and the results observed demonstrate substantial equivalence with the predicate device.

Substantial Equivalence

The Horizon Perinatal Care Surveillance and Archival System has the same intended use, indications for use, technological characteristics, and principles of operation as its predicate device. The minor technological differences between Horizon Perinatal Care Surveillance and Archival System and its predicate device raise no new issues of safety or effectiveness. Verification and validation testing demonstrate that Horizon Perinatal Care Surveillance and Archival System functioned as intended. Thus, Horizon Perinatal Care Surveillance and Archival is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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McKesson Information Solutions LLC
c/o Steven B. Datloff, M.D., J.D.
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

Re: K102263
Trade Name: Horizon Perinatal Care Surveillance and Archival System
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: April 29, 2011
Received: May 2, 2011

Dear Dr. Datloff:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102263

Device Name: Horizon Perinatal Care Surveillance and Archival System

Intended Use:

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Indications for Use:

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- Provides remote access to the HPC S&A system.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102263

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