SEP 26 2011

GE Healthcare

Centricity® Perinatal and Centricity Intensive Care - 510(k) Premarket Notification

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2011-Mar-04
Submitter:	GE Healthcare – HCIT 540 W Northwest Highway Barrington, IL, USA, 60010-3076
Primary Contact Person:	Nicole Landreville USA Premarket Regulatory Affairs Leader GE Healthcare, QARA Regions – Americas 3000 North Grandview Boulevard #W450 Waukesha, WI, USA, 53188 T: (289) 208-2365 F: (414) 918-4498
Secondary Contact Person:	Jeme Wallace Director Regulatory Affairs GE Heathcare IT 540 W Northwest Highway Barrington, IL, USA, 60010-3076 T (847) 277-4468 F (847) 939-1446
Device/Trade Name:	Centricity® Perinatal and Centricity Intensive Care
Common/Usual Name:	Centricity® Perinatal and Centricity Intensive Care, CPN, Centricity Perinatal
Classification Names: Product Code:	Perinatal monitoring system and accessories. HGM 884.2740
Predicate Device(s):	Centricity® Perinatal and Centricity Intensive Care [Formally known as Quantitative Sentinel (QS) System]

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Device Description:	The Centricity® Perinatal and Centricity Intensive Care is a data management tool. The basis for this submission is a modification to a legally marketed device. Both the proposed device intended use and indications for use statements are equivalent to that of the predicate device and have been reworded to improve clarity. Since 1999, Data Management Computer Systems and Technology have evolved. GEHC has modified the device by incorporating "state of the art" technology. The most significant changes being listed are: Overall product enhancements for security and privacy (to support HIPAA), interoperability enhancements, clinician notification enhancements, removal of some features only supplied on the old OS/2 platform version, keeping up with technology changes with respect to Windows Operating system, etc. On their own, none of these changes would have triggered a 510k submission. However, it was deemed important to clarify the Intended Use and Indications for use as well as to notify FDA of the current product state since many changes were made to keep up with the evolution of technology.

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Intended Use:	Centricity® Perinatal and Centricity Intensive Care is intended to be used as a data management tool with which a medical institution may define electronic forms to acquire device data and to document, annotate, display, store, print, export and retrieve patient/clinical practice information. This product is a primary tool for documentation as well as an adjunct tool for surveillance. Indications for Use: The Centricity Perinatal and Centricity Intensive Care (CPN-CIC) is a clinical information system used to manage clinical data. The CPN-CIC may be used in the following clinical settings such as: • Labor and Delivery (Antepartum, Intrapartum) • Postpartum • Newborn Nursery • Critical Care Units (Neonatal Intensive Care, Adult Intensive Care) The CPN-CIC can be used in the hospitals, physician offices, and outpatient clinics where the system can accept and display data from the following sources such as: • Physiologic devices • External hospital and clinical information systems NOTE: This product does not replace clinical observation and evaluation of the patient at regular intervals by a qualified healthcare provider, who will make diagnoses and decide on treatments and/or interventions. Features of the product are intended to support clinical decision making and should be used in combination with other clinical inputs, such as real time patient observation, physical exam findings and information contained within other systems or recording tools. The product is not intended to be used as a primary monitoring or diagnostic device.
Technology:	The Centricity® Perinatal and Centricity Intensive Care employs the same fundamental scientific technology as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ms. Jeme Wallace
Director Regulatory Affairs
GE Healthcare
540 W Northwest Highway
BARRINGTON IL 60010

SEP 26 2011

Re: K111614
Trade/Device Name: Centricity® Perinatal and Centricity Intensive Care
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, MSX
Dated: August 19, 2011
Received: August 23, 2011

Dear Ms. Wallace:

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

510(k) Number (if known): K111614

Device Name: Centricity® Perinatal and Centricity Intensive Care

Intended Use:
Centricity® Perinatal and Centricity Intensive Care is intended to be used in clinical departments of healthcare delivery systems such as Labor and Delivery, Postpartum Maternal Care, Newborn Nursery, critical care units including Neonatal Intensive Care Units (NICU), and may also be used in physician offices and outpatient clinics. This product is primarily intended to serve the purpose of electronic documentation of clinical data and is designed to accept, transfer, display, calculate, store and manage clinical data. System capabilities provide the user with the ability to acquire data from medical devices and to document, annotate, display, store, print, export and retrieve patient/clinical practice information. This product is intended for professional use only.

Indications for Use:
The Centricity Perinatal and Centricity Intensive Care (CPN-CIC) is a clinical information system used to manage clinical data. The CPN-CIC may be used in the following clinical settings such as:

- Labor and Delivery (Antepartum, Intrapartum)
- Postpartum
- Newborn Nursery
- Critical Care Units (Neonatal Intensive Care, Adult Intensive Care)

The CPN-CIC can be used in the hospitals, physician offices, and outpatient clinics where the system can accept and display data from the following sources such as:
• Physiologic devices
• External hospital and clinical information systems

NOTE: This product does not replace clinical observation and evaluation of the patient at regular intervals by a qualified healthcare provider, who will make diagnoses and decide on treatments and/or interventions. Features of the product are intended to support clinical decision making and should be used in combination with other clinical inputs, such as real time patient observation, physical exam findings and information contained within other systems or recording tools. The product is not intended to be used as a primary monitoring or diagnostic device.

Prescription Use_X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 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, Gastro-Renal, and Urological Devices
510(k) Number K111614

Prescription Use (Per 21 CFR 801.109)