JUL 19 2011

Premarket Notification 510(k) Summary

As required by section 807.92

Mini Telemetry System

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

Date: 24 Feb, 2011

Submitter: Wipro GE Healthcare Private Ltd.
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bangalore, INDIA 560067

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Device: Trade Name: MINI TELEMETRY SYSTEM

Common/Usual Name: Maternal Fetal Telemetry System

Classification Names: Device Classification name: System Monitoring Perinatal

Product Code: Classification Product Code: HGM

Predicate Device(s): Corometrics Model 330 Fetal Maternal Telemetry System K910260

Device Description:	The Mini Telemetry System provides a wireless means of transmitting heart rate and uterine activity signals from an ambulatory mother to a fetal or maternal/fetal monitor. It includes receiver (RX 2051412-004) and transmitter (TX 2051411- 004) subsystems. The system monitors fetal heart rate through ultrasound Doppler technology, ECG (Fetal ECG or Maternal ECG), and uterine activity (TOCO or IUPC) signals individually or in combination. The transmitter stays along with mother acquiring data from transducers and transmitting it to the remote Receiver placed next to the monitor in the room.The Mini Transmitter is carried by the

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	mother using the strap mechanism. One end of the transducers are connected to the transmitter and the other end comes in contact with the mother to acquire data. This system acquires and transmits data wirelessly to the receiver. The Mini Telemetry system itself is an accessory to the main fetal/maternal fetal monitor. The Mini Telemetry system is compatible with the following Corometrics brand monitors:

Name of the Monitors	**510(k) Number**
CORO 170 Series fetal monitors	K993751 / K991905
CORO 120 Series Maternal fetal monitors	K0332252
CORO 250 Series Maternal fetal monitors	K050583
CORO 250cx Series Maternal fetal monitors	K072976

Indication for Use:

The Mini Telemetry system is intended to transmit fetal heart rate and uterine activity signals from an ambulatory mother to a fetal or maternal fetal monitor during the ante partum period and during labor. The system allows ultrasound fetal heart rate, FECG, MECG and uterine activity signals to be monitored individually or in combination.

The Mini Telemetry system is intended for use under the direct supervision of a licensed healthcare practitioner in a defined coverage area.

The Mini Telemetry device is not intended to be operated in mobile vehicles including ambulances or other vehicles associated with health care facilities.

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Technology: The Mini Telemetry employs the same fundamental scientific technology as its predicate device, which includes: analogue acquisition section, voltage controlled oscillator and RF transmission.

The Mini Telemetry design includes the same parametric acquisition sections as in the predicate device for Ultrasound, Uterine Activity and Electrocardiogram with additional display capability, incorporating semiconductors to reduce the size and weight of the system.

The same Radio Telemetry module from the predicate device is used in Mini Telemetry System.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

Verification and Testing activities establish the performance, functionality, usability, safety, and reliability characteristics of Mini Telemetry System.

The table below indicates the names of the Standard and their specific location in the 510(k) document.

Standards No:	Standards Organization	Standards Title	Location
IEC 60601-1 : 1988 + A1 1991 + A2 1995	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety	17 Annex D.1
IEC 60601-1-6, 2006	IEC	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability	18 Annex E.12
ISO 10993-1, 2009	ISO	Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing within a Risk Management Process	15 Annex B.1
IEC 60601-1-2, 2007	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility	17 Annex D.2
IEC 62304, 2006	IEC	Medical Device Software, Software LifeCycle Process	Refer to Section 16
IEC 60601-2-37 : 2001+ A1 : 2004, +A2 : 2005	IEC	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	18 Annex G.2
IEC 60601-2-49, 2001	IEC	Particular requirements for the safety of multifunction patient monitoring equipment	18 Annex G.2
IEC 60601-1-	IEC	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	18 Annex G.3

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FCC 47 CFR Part 95; Part 95: Personal Radio Services	FCC	Personal Radio Services Subpart H: WMTS Subpart I: MEDRADIO	18 Annex G.1
Standards No:	Standards Organization	Standards Title	Location
FCC 47 CFR Part 2	FCC	FCC SAR Test Report	18 Annex G.4

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews

Summary of Simulated Use Setting:

The Design verification of Mini Telemetry System has been divided into several protocols that include electrical, mechanical, safety Testing, reliability, and system design verification protocols.

The performance testing included testing on unit level, system level, as well as usability, biocompatibility, and safety parameters.

The results of the Design verification testing protocols have been documented in Section 18 of this 510(k) application.

The results demonstrate that the Mini Telemetry system meets all design requirements and performance claims.

The subject of this premarket submission, Mini Telemetry System, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Mini Telemetry Systems to be as safe and as effective as the predicate device, and the performance to be substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Wipro GE Healthcare Private Ltd.
c/o Ms. Agata Smieja
Regulatory Affairs Director
GE Healthcare
8880 Gorman Road
LAUREL MD 20723-5800

JUL 19 2011

Re: K110556
Trade Name: Mini Telemetry System
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring and accessories
Regulatory Class: II
Product Code: HGM
Dated: June 17, 2011
Received: June 17, 2011

Dear Ms. Smieja:

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

510(k) Number (if known): K110556

Device Name: Mini Telemetry System

Indications for Use:

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The Mini Telemetry device is not intended to be operated in mobile vehicles including ambulances or other vehicles associated with health care facilities.

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 K110556