DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Clinical Computer System, Inc.
% Mr. William Sammons
Sr. Project Engineer, Sr. Reviewer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

JUN 14 2012

Re: K121208
Trade/Device Name: OBIX Perinatal Data System 7.0
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: May 30, 2012
Received: May 31, 2012

Dear Mr. Sammons:

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

clinical computer systems incorporated

Indications for Use

510(k) Number (if known): K121208

Device Name: OBIX Perinatal Data System 7.0

Indications for Use:

For obstetrical patients, the OBIX Perinatal Data System 7.0 provides health care professionals a method to display and archive electronic fetal monitor data and manage demographic information and documentation.

The intended use of the OBIX system is displaying and recording fetal and maternal physiological data obtained from electronic fetal monitors. The OBIX system also has these capabilities:

- Monitors fetal and maternal physiological data obtained from standard electronic fetal monitors and accompanying accessories and captures it on permanent storage media.
- Displays the monitored data for one or more patients in the patient rooms and at other locations as required by the hospital.
- Supports patient management activities, including note entry onto the electronic fetal monitor tracings and into the medical record.
- Provides tools that assist clinicians in evaluating fetal heart rate patterns.
- Generates flowsheets and graphs based on the notes recorded for the patient.
- The optional Registration Interface registers patients in the OBIX system directly from the hospital's admissions system. Patients can also be registered in the OBIX system manually, when necessary.
- Displays the Status Board (chalkboard), which shows patient rooms and key data elements in real-time format. The Status Board is typically displayed at one or more central locations, usually at the central nurses' station.
- Provides optional remote access to patient monitoring and management activities through off-site workstations connected by a virtual private network (VPN) connection or a secure hospital Web page.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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)

Caroline Y Neuland
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121208

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