K121758

510(k) Summary

OCT 9 2012

Submitter's Name:	Cerner Corporation
Submitter's Address:	10234 Marion Park Drive Kansas City, MO 64137
Submitter's Telephone:	816-221-1024
Submitter's Contact:	Shelley S. Looby, Director Regulatory Affairs 816-201-1368 (office) 816-885-3069 (mobile) slooby@cerner.com
Date 510(k) Summary Prepared:	September 10, 2012

Trade/Proprietary Name:	Cerner *FetaLink+™* (Version 1.0)
Common/Usual Name:	*FetaLink+™*
Classification Name:	Obstetrical and Gynecological Monitoring Devices
Classification Regulation:	884.2740
Regulation Description:	Perinatal Monitoring System and AccessoriesProduct
Code:	HGM
Classification:	Class II

Predicate Device:	*AirStrip OB®*
Manufacturer:	AirStrip Technologies 335 E Sonterra Blvd Suite 200 San Antonio, TX 78258
510(k) Number:	K090269

Description of the Device

Cerner *FetaLink+* is the software application that runs on the user's iPhone or iPad. The application displays patient clinical waveform data including maternal heart rate, fetal heart rates, maternal oxygen saturation, maternal blood pressure, and uterine contractions. Within the application, the user can view annotations associated to waveform data. .

Statement of Intended Use

Cerner *FetaLink+* is a software-only application intended for use on iOS mobile devices by obstetrical healthcare clinicians to view near real time the simultaneous measurement of fetal heart rate(s) and uterine contractions waveforms in one view. *FetaLink+* transforms the ongoing measurements into a visual wave display which conveys the frequency, duration and relative strength of uterine contractions combined with the patient data of pregnant women in the antepartum and/or intrapartum phases of pregnancy.

Summary of the technological characteristics of the device compared to the predicate device

Information to support substantial equivalence claims is summarized below.

Company	Cerner Corporation	AirStrip Technologies
Model	*FetaLink+*	*Airstrip OB*
System Characteristics		
Operating System	IOS 5.1	IOS 5.0, Android, Blackberry, Windows Mobile
Operator Interfaces	Mobile hand-held device with touch screen and virtual keyboard	Mobile hand-held device with touch screen or keypad

Company	Cerner Corporation	AirStrip Technologies
Model	*FetaLink+*	*Airstrip OB*
Network Validation Required?	Yes. It is the customer's responsibility to perform network validation.	Yes. It is the customer's responsibility to perform network validation.
Patient List	View census (all laboring patients), grouped by location. Displays the following demographic information on the patient list: • Patient First Name • Patient Middle Name • Patient Last Name • Patient Age • Physician Name • Patient Photo	View census (all laboring patients), grouped by location. Displays the following demographic information on the patient list: • Patient First Name • Patient Middle Name • Patient Last Name • Patient Age • Physician Name
Target Population	Pregnant patients monitored on various fetal monitoring medical devices	Pregnant patients monitored on various fetal monitoring medical devices

Company	Cerner Corporation	AirStrip Technologies
Model	***FetaLink+***	***Airstrip OB***
Clinical Data	Displays the following clinical information relevant to pregnancy: • Gravida • Para • Maternal Temperature • Maternal Pulse • Maternal Systolic BP • Maternal Diastolic BP • Maternal SPO2 • Cervical Dilation • Cervical Effacement • Fetal Station • Fetal Count • Membrane Status • Epidural Status • EDD • EGA	Displays the following clinical information relevant to pregnancy: • Gravida • Para • Maternal Temperature • Maternal Pulse • Maternal Systolic BP • Maternal Diastolic BP • Maternal SPO2 • Cervical Dilation • Cervical Effacement • Fetal Station • Fetal Count • Membrane Status • Epidural Status • EDD
Live waveform data	Graphical display of fetal heart rates and contraction data in near real time. Specifically: Will display the following read-only waveform elements: • Baby 1 Heart Rate Waveform Data • Baby 2 Heart Rate Waveform Data • Baby 3 Heart Rate Waveform Data • Baby 4 Heart Rate Waveform Data • Maternal Uterine Activity Waveform Data • Annotations	Graphical display of fetal heart rates and contraction data in near real time. Specifically: Will display the following read-only waveform data elements: • Baby 1 Heart Rate Waveform Data • Baby 2 Heart Rate Waveform Data • Maternal Uterine Activity Waveform Data • Annotations

Company	Cerner Corporation	AirStrip Technologies
Model	*FetaLink+*	*Airstrip OB*
Historical view of waveform data	Ability to navigate to view historical waveform data of the current monitored episode. Specifically: Will display the following read-only historical waveform data elements: • Baby 1 Heart Rate Waveform Data • Baby 2 Heart Rate Waveform Data • Baby 3 Heart Rate Waveform Data • Baby 4 Heart Rate Waveform Data • Maternal Uterine Activity Waveform Data • Annotations	Ability to navigate to view historical waveform data of the current monitored episode. Specifically: Will display the following read-only historical waveform data elements: • Baby 1 Heart Rate Waveform Data • Baby 2 Heart Rate Waveform Data • Maternal Uterine Activity Waveform Data • Annotations

Like *Airstrip OB*, Cerner *FetaLink+* is designed to be used by obstetrical health providers in a clinical setting. Both systems share the capabilities listed below:

- Provide a dynamic near real time view of the graphical display of the relationship between fetal heart rates and contraction data which can be accessed remotely using a hand held device

---

Summary of Performance Testing

The testing performed was intended to ensure the functional requirements have been implemented and that hazards identified in the Device Hazard Analysis have been mitigated.

Cerner's validation demonstrated that all functional requirements and hazard analysis software mitigations for Cerner *FetaLink+* were executed and the expected results achieved. Based on the results of the testing performed, Cerner *FetaLink+* was evaluated to be a safe and effective device for use in a live patient environment.

As part of the development and release process, the software goes through internal testing, which includes the following:

- Unit Testing (Verification)
- Functional Testing (Validation)
- Regression Testing
- Exploratory Testing
- Assembly Testing

Conclusions

Functional testing, which validated that all functional requirements for the software have been met, were completed prior to formative and summative usability with no outstanding issues identified.

Formative and summative usability, which involved task-based walkthroughs and post-test questionnaire, evaluated possible use errors in the user interface. Based on the results, changes were implemented to mitigate identified use errors.

The results of summative usability and the mitigations applied based on those results show that residual risk has been reduced as low as reasonably practicable.

Interference testing was completed in order to identify and mitigate any risks of interference from clinical or non-clinical devices used in close proximity to the mobile device on which the software resides.

FetaLink+ has been found to be adequately safe and effective for the intended users, its intended uses, and use environments.

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

Ms. Shelley S. Looby, MT(ASCP)BB
Director, Regulatory Affairs/Quality Assurance
Cerner Corporation
10234 Marion Park Drive
KANSAS CITY MO 64137

OCT 9 2012

Re: K121758
Trade/Device Name: Cerner FetaLink+™
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: September 17, 2012
Received: September 19, 2012

Dear Ms. Looby:

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

Indications for Use

510(k) Number (if known): K121758

Device Name: Cerner *FetaLink+™*

Indications for Use:

Cerner *FetaLink+* is a software-only application intended for use on iOS mobile devices by obstetrical healthcare clinicians to view near real time the simultaneous measurement of fetal heart rate(s) and uterine contractions waveforms in one view. *FetaLink+* transforms the ongoing measurements into a visual wave display which conveys the frequency, duration and relative strength of uterine contractions combined with the patient data of pregnant women in the antepartum and/or intrapartum phases of pregnancy.

Prescription Use _X.__ AND/OR Over-The-Counter Use _n.a.__

(Part 21 CFR 801 Subpart D) (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)

09 Oct 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121758