DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 17, 2015

Mindchild Medical
% Leo Basta
Owner
NorthStar Biomedical Associates
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Re: K142883
Trade/Device Name: MindChild Meridian M100 Fetal Heart Rate Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: Class II
Product Code: HGM
Dated: September 30, 2014
Received: October 2, 2014

Dear Leo Basta,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

Benjamin Fisher, PhD.
Director
Division of Reproductive, Gastro-Renal,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142883

Device Name
MindChild Meridian M100 Fetal Heart Rate Monitor

Indications for Use *(Describe)*
The MindChild Medical Meridian M100 Fetal Heart Rate Monitor is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR). The MindChild Meridian M100 acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). FHR tracings are displayed onto a primary fetal monitor. In addition, the M100 synchronizes the TOCO transducer signal which is also displayed to the primary fetal monitor.

The MindChild Meridian M100 is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The MindChild Meridian is intended for use by healthcare professionals in a clinical setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**
**MindChild Meridian M100 Fetal Heart Rate Monitor**


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**Date Prepared**: March 14, 2015

**Trade Name**: MindChild Meridian M100 Fetal Heart Rate Monitor

**Regulation Name**: Perinatal monitoring system and accessories

**Classification Number**: 21 CFR 884.2740

**Product Code**: HGM

**Predicate Devices**: Meridian M1000 Monitor (K120018)

**Device Description:**

The Meridian M100 Fetal Heart Rate Monitor is a modification of the cleared M1000 Fetal Heart Rate Monitor (K120018). The modifications are ones that do not affect the intended use or the fundamental scientific technology. The M100 Fetal Heart Rate Monitor is an AC powered fetal heart rate (FHR) monitor. The product consists of a signal processor containing hardware circuitry and software which acquires and processes analog signals using external, abdominal electrode sensors. Software algorithms extract ECG morphology and monitor fetal heart rate.

The M100 connects to existing cleared fetal heart rate monitors with DECG (i.e., primary monitor) using the primary monitor's screen for display of fetal heart rate. The patient data is displayed real time on the primary monitor's display. The Meridian M100 is used as an accessory to a main/primary fetal monitor replacing the Doppler sensor on those monitors. The M100 is for use with the GE Corometrics 120 and the GE Corometrics 250 Fetal Monitors.

The M100 differs from the cleared M1000 in the following ways:

1. The M100 has connection ports for connection of the M100 to existing cleared fetal heart rate monitors. Through these connections, the M100 uses the existing primary monitor's display for fetal heart rate whereas the M1000 incorporates a 24" LCD display,
2. The M100 incorporates a standard input connection for a uterine contraction device. The M100 acts as a pass-through of this signal allowing for the uterine contraction data to be displayed on the primary monitor screen along with the fetal heart rate. The M1000 did not include this feature. Instead, viewing uterine contraction data required a separate monitor placed beside the M1000 device and viewing data on two screens. The M100 does not process uterine contraction signals but only synchronizes them to the fetal heart rate data.
3. The primary monitor, to which the M100 is connected, is used for DECG measurements using a fetal scalp electrode should that be necessary. The M1000 had a dedicated DECG connection and adapter for a fetal scalp electrode.
4. The M100 is set on a table top whereas the M1000 is housed within a roll-up cart.

The algorithm used in the M100 to acquire and process fetal ECG signals through externally placed abdominal electrodes is the same as that used and clinically validated in the cleared M1000 device.

**Indications for Use:**

The MindChild Medical Meridian M100 Fetal Heart Rate Monitor is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR). The MindChild Meridian M100 acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). FHR tracings are displayed onto a primary fetal

monitor.  In addition, the M100 synchronizes the TOCO transducer signal which is also displayed to the primary fetal monitor.

The MindChild Meridian M100 is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The MindChild Meridian is intended for use by healthcare professionals in a clinical setting.

## Device Characteristic Comparison

| Characteristic | M100 Fetal Heart Rate Monitor [current 510(k)] | M1000 Fetal Heart Rate Monitor – K120018 | Substantial Equivalence |
|---|---|---|---|
| **Device Photograph** |  Table top configuration |  Roller cart configuration | **Different footprint of the M100 allows for placement on the table top. Firmware for the M1000 is contained within a roller cart with drawer and display monitor. M100 device uses the display of the primary fetal heart rate monitor to which it is connected.**<br><br>**The software and firmware of the M100 and M1000 is identical varying only in regard to the system administrative software. The fetal heart rate algorithm remains the same.** |
| **Intended Use** | A fetal cardiac monitor used to monitor fetal heart activity during pregnancy and labor. | A fetal cardiac monitor used to monitor fetal heart activity during pregnancy and labor. | **Identical** |
| **Indications for Use** | The MindChild Medical Meridian M100 Fetal Heart Rate Monitor is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR). The MindChild Meridian M100 acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). FHR tracings are displayed onto a primary fetal monitor. In addition, the M100 synchronizes the TOCO transducer signal which is also displayed to the primary fetal monitor. The MindChild Meridian M100 is indicated for use | The MindChild Medical Meridian Fetal Heart Rate Monitor is an intrapartum fetal monitor that externally or internally measures and displays fetal heart rate (FHR). The MindChild Meridian acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). The MindChild Meridian may also be used to measure and display fetal heart rate using direct ECG (DECG) with a fetal scalp electrode. The MindChild Meridian is indicated for use on women who are at term (> 36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The | **Very similar. The differences don't affect the or effectiveness as all of the same functions can be operated either through the M100 or the primary monitor (should the invasive DECG using a fetal scalp electrode be clinically indicated.** |

| Characteristic | M100 Fetal Heart Rate Monitor [current 510(k)] | M1000 Fetal Heart Rate Monitor – K120018 | Substantial Equivalence |
|---|---|---|---|
| | on women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The MindChild Meridian is intended for use by healthcare professionals in a clinical setting. | MindChild Meridian is intended for use by healthcare professionals in a clinical setting. | |
| **Regulation Number** | 884.2740 | 884.2740 | **Identical** |
| **Display** | 2 inch LCD screen on front of unit for system only information. The M100 uses the display of the primary fetal heart monitor to display the fetal heart rate. | 24" diagonal real time LCD display (1900 x 1200 pixels) that graphically displays clinical parameters received from signal processors. Touch screen provides user with interface to control operation of unit. | **Identical information displayed. M100 utilizes the primary monitor to display fetal heart rate calculated from ECG signals collected via abdominal electrodes and calculated using the Meridian algorithm. The algorithm remains the same as the M1000.** |
| **Controls** | Power "On" button on rear side of the M100 to activate. | Power "On" button on front side of M1000 to activate. The LCD display incorporates "Action" buttons that are touch sensitive to control operation of the unit. | **Each unit has a power "On/Off" switch to activate the monitor. The M100 switch is located on the rear of the unit, whereas the M1000 is on the front of the unit. The M1000 also has control buttons on the display screen that operates certain functions of the M1000. The M100 utilizes the primary monitor to control the same functions when the M100 is attached.** |
| **Printer** | The M100 does not include an integrated printer; however, patient data including graphical display may be downloaded via the primary monitor to which the M100 is attached. | The Meridian Monitor does not include an integrated printer; however, patient data including graphical display may be downloaded via integral USB port to a standard USB jump drive for printing or transfer of data. | **Both systems allow for the same function. The M100 and the M1000 allow for downloading patient data and transfer of information. The proposed M100 accomplishes this through use of the primary monitor to which it is attached, whereas the cleared M1000 possesses this capability through a USB jump drive.** |
| **Front or top Connections** | There are six connectors on the front of the unit. Five of the connectors are for cable connections to the external electrode sensors including reference and ground. The sixth connector is for the connection of cleared TOCO uterine contraction devices. | There are five connectors on the front of the unit. All five of the connectors are for cable connections to the external electrode sensors including reference and ground. The fifth connector is also used for the connection to the optional fetal scalp electrode. | **Similar. Each unit has connections for the externally placed maternal abdominal electrodes used to acquire bioelectric signals of the fetal heart. The M100 provides a connection to TOCO uterine contraction accessories whereas the M1000 incorporates a connection for an optional** |

| Characteristic | M100 Fetal Heart Rate Monitor [current 510(k)] | M1000 Fetal Heart Rate Monitor – K120018 | Substantial Equivalence |
|---|---|---|---|
| | | | **fetal scalp electrode. These differences do not affect substantial equivalence as the M100 does not process uterine contraction data but instead passes the information on to the primary monitor whereas the M1000 was used in conjunction with a TOCO monitor and the user was required to review the FHR data on the M1000 in parallel with the uterine contraction data.** ***Functionally Identical.***<br><br>**Although the M100 does not incorporate the fetal scalp electrode connection, it does allow for the use of a fetal scalp electrode if indicated using the connection on the primary monitor.** ***Functionally Identical.*** |
| **Rear Connections** | Power connection and connections to the primary monitor. | Power connection. | **Because the M100 utilizes the display of the primary monitor for displaying fetal heart rate and uterine contraction information, the device incorporates connection ports to couple the two monitors. Functionally, the M100 and M1000 are very similar and allow for the provision of the identical information to the user.** |
| **Side Connections** | No connections | No connections | **No impact on substantial equivalence.** |
| **Input Voltage Range** | 120 VAC ±10% | 120 VAC ±10% | **No impact on substantial equivalence.** |

| Characteristic | M100 Fetal Heart Rate Monitor [current 510(k)] | M1000 Fetal Heart Rate Monitor – K120018 | Substantial Equivalence |
|---|---|---|---|
| **Frequency** | 60 Hz | 60 Hz | **No impact on substantial equivalence.** |
| **Method** | Acquisition of fetal ECG signals via multiple **external abdominal sensor electrodes**, which are then processed on the signal processor which is comprised of the signal processing card and system controller.<br><br>Direct ECG (DECG) acquisition using FDA cleared fetal scalp probes composed of a reusable DECG leg plate cable, leg plate attachment electrode and Philips Spiral Electrode. Connection on the primary monitor is used for the fetal scalp electrode.<br><br>TOCO connection is incorporated in the M100. The M100 does not process the uterine contraction information. It syncs the information with the fetal heart rate and passes the information on to the primary monitor. | Acquisition of fetal ECG signals via multiple **external abdominal sensor electrodes**, which are then processed on the signal processor which is comprised of the signal processing card and system controller.<br><br>Direct ECG (DECG) acquisition using FDA cleared fetal scalp probes composed of a reusable DECG leg plate cable, leg plate attachment electrode and Philips Spiral Electrode.<br><br>M1000 monitor used in parallel while the physician looks at a TOCO monitor while reviewing the fetal heart rate on the M1000. | **The changes made resulting in the M100 device have no adverse impact on substantial equivalence.** |
| **Measurement Range** | 50 - 240 BPM; abdominal sensor mode<br><br>DECG Mode dependent on primary monitor. | 50 - 240 BPM; abdominal sensor mode<br><br>50 - 240 BPM; DECG Mode | **No impact on substantial equivalence.** |
| **Signal Processing** | Analog to digital | Analog to digital | **No impact on substantial equivalence.** |

| Characteristic | M100 Fetal Heart Rate Monitor [current 510(k)] | M1000 Fetal Heart Rate Monitor – K120018 | Substantial Equivalence |
|---|---|---|---|
| **Safety** | Patient protection isolation barrier provides 4KVDC of galvanic isolation for all patient input connections. The cables that connect directly to the patient pass through this isolation barrier.<br><br>Will be certified to comply with FDA recognized standards pertaining to electrical safety and EMC. | Patient protection isolation barrier provides 4KVDC of galvanic isolation for all patient input connections. The cables that connect directly to the patient pass through this isolation barrier.<br><br>Will be certified to comply with FDA recognized standards pertaining to electrical safety and EMC. | **No impact on substantial equivalence.** |
| **Software** | Microsoft Windows 7 embedded operating system customized to support specific Meridian hardware. Proprietary MindChild ECG algorithm provides processing and filtering to extract fetal ECG and calculate fetal heart rate. Software modification allowing for syncing uterine contraction signal with fetal heart rate (does not alter or manipulate uterine contraction data). | Microsoft Windows 7 embedded operating system customized to support specific Meridian hardware. Proprietary MindChild ECG algorithm provides processing and filtering to extract fetal ECG and calculate fetal heart rate. | **No impact on substantial equivalence.** |
| | Graphical and numeric data displayed on primary monitor display. Patient data may be stored on primary monitor and downloaded or printed using primary monitor's functions. | Graphical and numeric data display on touch screen monitor. Individual patient data may be stored on the unit and downloaded via user supplied USB Jump drive for inclusion into hospital electronic records. Hard copies of graphical display may be printed in standard format. | **No impact on substantial equivalence.** |

**Performance Testing**:

Descriptive information, laboratory bench testing, electrical safety/EMC testing, and software validation were provided to demonstrate the device meets its design specifications, performs as intended, is safe for its intended use and that the modifications made from the M1000 device do not adversely affect safety and effectiveness.

The following testing was performed:

Hardware

| Test | Purpose | Results |
|---|---|---|
| Dimensional Verification | To verify products meets specified dimensions and weight | Met design specification |
| Fetal Heart Rate Output | Verify FHR output waveform for both minimum and maximum amplitude fetal heart output. | Met design specification |
| TOCO Output | Verify Toco output voltage for pressure application | Met design specification |
| Packaging Testing | Verification of packaging and labeling. | Met design specification |
| Cable Pull Strength | Verify the cable connections are maintained when a 5 ft/lb. load is applied. Results are force applied to each of the patient cable connector extraction. | Met design specification |
| Drop Test | Verification that unit could sustain drop | Met specification |
| Push Test | Verify mechanical strength of enclosure by applying a 250N force to all sides and bottom of enclosure | Met specification |
| Cleaning | Verify that cleaning, disinfecting, and sterilizing the monitor in accordance with the instructions for doing so in the Operator's Manual and Service Manual do not create any hazards or hazardous situations. Ensure that cleaning substances are compatible with the M100. | Met specification |
| Software Validation | Verify that all software modifications made performed as intended. Complete re-validation of the software was performed. | Software validation demonstrated that the software performed according to design specifications, met requirement specifications and that there were no unintended effects due to any software modifications made. |

Biocompatibility Testing

Biocompatibility testing was not required as the M100 using the same patient contacting materials as that used in the cleared M1000 device.

Primary Monitor Compatibility

The M100 Monitor is intended to be used with the currently marketed GE Corometrics 120 and 250 Fetal Monitors. Compatibility testing was performed using the M100 monitor with each of the marketed primary monitors. Testing demonstrated the M100 is compatible with each of these monitors.

Electrical Safety and EMC

In addition, electrical safety, electromagnetic compatibility, and usability testing was performed in accordance with the following standards. The M100 monitor met all test criteria.

1) IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance; IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
2) IEC 60601-1-2: ed3.0 (2007-03), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (***FDA recognized number: 19-1***)
3) IEC 60601-1-6:2010 (Third Edition), Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability (***FDA recognized number: 5-85***)
4) IEC 60601-2-49 (Second Edition): 2011, Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
5) IEC 62366:2007(ed.1), Medical devices - Application of usability engineering to medical devices (***FDA recognized number: 5-67***)

Clinical Validation

The algorithm responsible for calculating fetal heart rate in the M100 Monitor is the same as that used in the cleared M1000 monitor. Further, the signal acquisition components (external electrodes) and signal processing software remain the same. The clinical validation of the software responsible for calculating FHR from fECG signals was performed in support of the cleared 510(k) for the M1000. This clinical validation is directly applicable to the modified design as the signal acquisition components (external electrodes) and the signal processing software and algorithm remains the same in the

modified M100 device. Therefore further clinical validation was not necessary for the modified device.

**Summary of Substantial Equivalence**:

The design, intended use, principles of operation, and technological characteristics of the MindChild Meridian M100 device are substantially equivalent to those of the already cleared M1000 device. Substantial equivalence is based upon descriptive characteristics of the modifications and upon the testing conducted and summarized in this 510(k). The changes made resulting in the M100 device do not change the device's intended use or the fundamental scientific technology used and the testing performed in support of this notification demonstrate that the M100 device is substantially equivalent to the M1000 device.