K120018

510(k) Summary
MindChild Medical Meridian Monitor

SEP 19 2012

Submitter:

MindChild Medical
1600 Osgood Street, #2-17
North Andover, MA 01845
Phone: 978.975.1160
Fax: 978.688.8875

Contact Person:

Leo Basta
NorthStar Biomedical Associates
755 Westminster St., Unit 120
Providence, RI, 02903
Phone: 617.834.9866
lbasta@northstarbiomedical.com

Date Prepared: August 18, 2012

Trade Name: MindChild Medical Meridian Monitor

Regulation Name: Perinatal monitoring system and accessories

Classification Number: 21 CFR 884.2740

Product Code: HGM

Predicate Devices: Monica Healthcare AN24 (K101801)

HP M1350A Fetal Monitor (K900480)

Device Description: The MindChild Medical Meridian 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. Data is stored locally for retrieval in an off-line mode. The patient data is displayed real time on a touch screen LCD display monitor. Data may be printed out offline for permanent hard copy records. The system also possesses the ability to acquire and analyze signals

from a fetal scalp electrode using the device's direct ECG (DECG) capability. The entire system is housed within a medical grade roll-up cart. The device is intended to be used in a hospital environment by trained medical staff.

Intended 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 MindChild Meridian is intended for use by healthcare professionals in a clinical setting.

Functional Testing:

Descriptive information, laboratory bench testing, electrical safety/EMC screening, software validation, and a biocompatibility assessment were provided to demonstrate the device meets its design specifications, performs as intended, and is safe for its intended use.

In addition, a clinical validation of the Meridian algorithm responsible for calculating FHR from fECG signals was performed. For this validation of the algorithm, fetal ECG signals were acquired and recorded using the Meridian Monitor technology and HP M1350A Fetal Monitor/FSE simultaneously. The HP M1250A Fetal Monitor/FSE was the comparator for the clinical validation study. The Meridian Monitor signals were subjected to analysis by the Meridian algorithm to calculate fetal heart rate. The resulting heart rates were compared to heart rates calculated using HP M1350A Fetal Monitor/FSE.
The analyses performed included FHR accuracy and percent successful recordings (i.e., # comparator signals/ # of Meridian signals x 100). This algorithm validation demonstrated that in either mode (abdominal electrode or DECG), the fetal heart rates calculated using the Meridian Monitor algorithm were close to the comparator's fetal heart rate calculations within a clinically acceptable number of beats per minute (BPM). There were no

statistically significant differences across different BMI groups analyzed. In addition, for all signals recorded with the comparator FSE device, the Meridian technology provided a successful signal reading on at least 94% of the signals.

Lastly, a single Bland Altman (BA) difference plot was generated for the Meridian Monitor FHR calculations versus those calculated using the Gold Standard device for each patient and a root mean square (RMS) error was determined. A BA difference plot is a scatter plot of the difference between the device and Gold Standard measurements versus the Gold Standard measurement. RMS error is the square root of the mean of the squared differences. The mean RMS error of 5 BPM (Beats Per Minute) for the Meridian algorithm is similar to results observed in other FDA cleared fetal heart rate monitors.

Device Characteristic Comparison

Characteristic	Proposed MindChild Meridian Device – K120018	Monica AN24, Monica Healthcare – K101801
Indications 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 MindChild Meridian is intended for use by healthcare professionals in a clinical setting.	The Monica AN24 is an intrapartumn maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal EGG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 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 AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.
Method	Acquisition of fetal ECG signals via external abdominal sensor electrodes. From these signals the fetal heart rate is extracted. Also may use direct ECG (DECG) acquisition using a fetal scalp electrode.	The electrical signals are passively monitored on three channels using external sensor electrodes placed on the pregnant abdomen. in specific locations. From these electrical signals the Fetal Heart Rate (FHR) are continuously extracted and displayed. No DECG option.
Software	Proprietary algorithm to calculate heart rate.	Proprietary algorithm to calculate heart rate.
Signal Processing	Analog to digital	Analog to digital
Display	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.	Ability to download data to PC or view via optional 15" cart mounted monitor or 10" mobile touch screen.
Controls	Power "On" button on control unit activates main operating screen on LCD display. On-screen display buttons to adjust various parameters.	On/Off switch, "Event" button, battery status, signal quality, memory status.
Connections	Five connectors for electrode leads and optional fetal scalp electrode, standard USB connector, standard AC plug and power connection	Electrode leads connector attaches to the top of the unit.
Input Voltage Range	85 - 264 VAC	AN24 and optional mobile 10" viewing monitor (VS10) - Battery operated
Frequency	50/60 Hz	Battery operated
Measurement Range	80 - 240 BPM; abdominal sensor mode, 30 - 50 BPM; DECG Mode	UNK
Safety	Complies with FDA recognized standards pertaining to electrical safety. Complies with FDA recognized standards pertaining to electrical safety and EMC.	Complies with FDA recognized standards pertaining to electrical safety. Complies with FDA recognized standards pertaining to electrical safety and EMC.

Summary of Substantial Equivalence:

The design, intended use, principles of operation, and technological characteristics of the MindChild Meridian device are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon descriptive characteristics of the various cited predicate devices and upon the testing conducted to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices in terms of its ability to monitor fetal heart rate using its abdominally placed external electrode sensors. In addition, fetal heart rate monitoring through the device's DECG mode was demonstrated to be substantially equivalent to that of marketed devices.

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

MindChild Medical
% Mr. Leo Basta
Owner
NorthStar Biomedical Associates
755 WestMinster Street, Unit 120
PROVIDENCE RI 02903

SEP 19 2012

Re: K120018
Trade/Device Name: MindChild Meridian Fetal Heart Rate Monitor
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: September 14, 2012
Received: September 17, 2012

Dear Mr. 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 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

INDICATION FOR USE

510(k) Number (if known): K120018 ~~Not Assigned~~

Device Name: MindChild Meridian Fetal Heart Rate Monitor

Indications 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 MindChild Meridian is intended for use by healthcare professionals in a clinical setting.

Prescription Use: __X__ AND/OR Over-The Counter Use: _____
(Per 21 CFR 801 Subpart D)..... (Per 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)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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