



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

January 12, 2017

Mindchild Medical  
% Leo Basta  
Owner  
Northstar Biomedical Associates  
93 Benefit Street  
Providence, Rhode Island 02904

Re: K161902  
Trade/Device Name: Meridian M110 Fetal Monitoring System  
Regulation Number: 21 CFR 884.2740  
Regulation Name: Perinatal Monitoring System and Accessories  
Regulatory Class: Class II  
Product Code: HGM  
Dated: December 16, 2016  
Received: December 19, 2016

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,

**Benjamin R. Fisher -S**

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)  
K161902

Device Name  
Meridian M110 Fetal Monitoring System

### Indications for Use (Describe)

The Meridian M110 Fetal Monitoring System is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR), maternal heart rate (MHR), and uterine contractions (UA). The Meridian M110 Fetal Monitoring System acquires and displays the FHR and UA from abdominal surface electrodes that detect the fetal ECG signals, maternal ECG signals, and of uterine muscle contraction signals. Tracings of FHR and UA are displayed onto a primary fetal monitor.

The Meridian M110 Fetal Monitoring System is indicated for use on women who are at  $\geq 37$  completed weeks, in labor, with singleton pregnancies using surface electrodes on the maternal abdomen. The Meridian M110 Fetal Monitoring System is intended for use by health care 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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