FOR IMMEDIATE RELEASE – November 16, 2015 MindChild Medical, Inc. Announces filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M110 Line of Non- Invasive Fetal Heart Rate Monitors

MERIDIAN M110 Provides Continuous Non-Invasive Fetal and Maternal Monitoring Using Surface Electrodes That Detect Fetal ECG (fECG), Fetal Heart Rate (FHR), Maternal Heart Rate (MHR), and Uterine Contractions (UA)

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced that it has filed a 510(k) pre-market notification with the US Food and Drug Administration (FDA) for its MERIDIAN Model M110 non-invasive Fetal Heart Monitor[1,2,3]. MindChild previously announced 510(k) pre-market clearance of the MERIDIAN M100 fetal monitor. MindChild anticipates entering the US market with the MERIDIAN family of fetal monitor products following the FDA pre-market clearance of the current 510(k) notification. Additional pre-market regulatory filings are anticipated during 2016.

The MindChild Medical Meridian M110 Fetal Heart Rate Monitor is an intrapartum fetal monitor that non-invasively measures and displays fetal heart rate (FHR), maternal heart rate (MHR), and uterine contractions (UA). The MindChild Meridian acquires and displays the FHR, MHR 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 MindChild Meridian M110 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 health care professionals in a clinical setting.

According to Michael Ross, MD, MPH[4], Distinguished Professor of Obstetrics and Gynecology and Public Health, Geffen School of Medicine at UCLA Fielding School of Public Health at UCLA, “The Meridian M110 Fetal Heart Monitor has to potential to consolidate 4 separate fetal and maternal monitoring technologies into one, non-invasive method.” Dr. Ross continued, “There are risks associated with the invasive methods of fetal heart rate detection and maternal uterine contraction monitoring. The M110 eliminates those risks. The current non-invasive technique for fetal heart monitoring is limited by maternal Body Mass Index (BMI) and the clinical data from the M110 and the preceding M100 suggest that BMI will not be a limitation in the accurate monitoring of fetal heart rate. Most critically, both M100 and M110 have heart rate detection technology which can discriminate between similar fetal and maternal heart rates, a critical capability which I look forward to seeing in the clinic.”

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[1] MindChild received 510(k) pre-market clearance for the MERIDIAN M1000 Fetal Heart Monitor September 19, 2012. MERIDIAN M1000 is a stand-alone Fetal heart Rate Monitor.

[2] MERIDIAN Fetal Heart Monitor is protected by patents, both issued and pending.

[3] MERIDIAN 100 Fetal Heart Monitor received 510(k) pre-market clearance April 17, 2015.

[4] Michael Ross, MD, MPH is a member of the MindChild Clinical Advisory Board

The Meridian M100 and M110 Fetal Heart Monitors[5] are intended to be compatible with existing fetal monitoring systems, facilitating rapid adoption by clinicians where MERIDIAN is commercially available. The Meridian M110 and M100 Fetal Heart Monitors are designed for women who are at term (> 36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

About Michael Ross, MD, MPH
Michael Ross is Professor of Obstetrics and Gynecology at the Geffen School of Medicine at UCLA and a practicing maternal fetal medicine physician who has extensively studied fetal physiology and fetal responses to hypoxia. He is the co-author of the textbook Fetal Monitoring Interpretation, (Lippicott Williams and Wilkins, 2010).

Previous Announcements
On April 19, 2015, MindChild Medical, Inc. announced clearance of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M100 Line of Non-Invasive Fetal Heart Rate Monitors

On November 11, 2014, MindChild Medical, Inc., announced the filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M100 Line of Non-Invasive Fetal Heart Rate Monitors

On April 8, 2014, MindChild Medical, Inc., announced the 1,000th successful non-invasive fetal heart monitoring session utilizing the MERIDIAN™ Fetal Heart Monitor

On May 1, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 61st Annual Meeting for the American College of Obstetricians and Gynecologists (ACOG) in New Orleans.

On February 13, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 33rd Annual Meeting for the Society for Maternal Fetal Medicine (SMFM) in San Francisco, CA.

On November 5, 2012, MindChild Medical, Inc., and The University of Oxford announced a Sponsored Research Agreement for the Development of Innovative Signal Processing Software for Fetal and Maternal Monitor with the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor.

On September 25, 2012, MindChild announced clearance of a 510(k) Pre-Marketing Notification with the US Food and Drug Administration (FDA) for the MERIDIAN™ M1000 Non-Invasive Fetal Heart Rate Monitor.

On June 18, 2012, MindChild announced the appointment Thomas Garite, M.D. to the Clinical Advisory Board for the MERIDIAN Line of Non-Invasive Fetal Heart Rate Monitors.

[5] MERIDIAN is supplied with single-use proprietary electrodes designed to monitor fetal heart rate.

On June 11, 2012, MindChild announced Results of National Fetal Monitoring Market Survey.
On February 22, 2012, MindChild reported formation of a Clinical Advisory Board for the MERIDIAN™ Line of Non-Invasive Fetal Heart Rate Monitors.

On February 6, 2012, MindChild reported filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ Line of Non-Invasive Fetal Heart Rate Monitors.

About the MERIDIAN M110 and M100 Non-Invasive Fetal Heart Rate Monitor

The **MindChild Medical Meridian M110** Fetal Heart Rate Monitor is an intrapartum fetal monitor that non-invasively measures and displays fetal heart rate (FHR), maternal heart rate (MHR), and uterine contractions (UA). The MindChild Meridian acquires and displays the FHR, MHR 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 MindChild Medical Meridian M110 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. MERIDIAN M100 is designed for women who are at term (> 36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. MERIDIAN is intended for use by healthcare professionals in a clinical setting.

About the Fetal Heart Monitoring Market

Over 85%[6] of the 4,000,000[7] live births occurring in the US during 2011 required fetal monitoring during labor and delivery. Current non-invasive Doppler, employing ultrasound to detect FHR is subject to loss of fetal heart rate due to maternal/fetal movement[8]. Fetal Scalp Electrodes (FSE) that connect directly to the fetus during the later stages of labor and delivery are associated with increased risk of maternal/fetal infection[9]. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US[10], representing an investment of over $700,000,000[11]. MERIDIAN has been developed to provide uninterruptible fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

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[6] "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

[7] http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf

[8] Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

[9] American Family Physician, 1992 Feb;45(2):579-82

[10] http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html

[11] Company estimates.