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MindChild Medical, Inc. Announces Clearance of a 510(k) Pre-Marketing Notification with the US Food and Drug Administration (FDA) for the MERIDIAN™ M110 Fetal Monitoring System

MERIDIAN Adds Uterine Contraction Monitoring to its Continuous Non-Invasive Fetal Heart Rate Technology Using Surface Electrodes

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced that it has received clearance for its Pre-Marketing Notification (510(k)) from the US Food and Drug Administration (FDA) for its MERIDIAN™ M110 non-invasive fetal heart monitor. MindChild anticipates entering the US market with MERIDIAN now that it has received the FDA clearance.

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 FHR, MHR and UA from abdominal surface electrodes that detect the fetal ECG signal, maternal ECG signal, and the uterine muscle contraction signal. 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 ≥ 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.

“We are thrilled to have reached this milestone”, stated Bill Edelman, CEO. He continued, “MERIDIAN M110 Fetal Monitoring System is the latest in a series of non-invasive fetal monitor technologies developed by MindChild that are intended to provide the healthcare community enhanced monitoring capabilities for both fetal heart rate , maternal heart rate and uterine contraction, with a single set of disposable abdominal surface electrodes. The Meridian M110 has the potential to provide essential fetal monitoring, replacing four separate monitoring technologies now in use world-wide. We anticipate significant clinical interest for this innovative technology in the markets where MERIDIAN will be cleared for commercial distribution.”

Adam Wolfberg, M.D., Chief Medical Officer for MindChild stated, “This FDA pre-market clearance delivers a highly-reliable fetal monitor to the obstetric community. In the coming months and years, MindChild will exploit this technology to improve the safety of obstetrics, and hand a new diagnostic device to obstetricians and pediatric cardiologists.”

Previous Announcements

On December 7, 2015, MindChild Medical, Inc. announced Receipt of Certificate of Registration by BSI Group America Inc., Under the International Organization for Standardization (ISO) 13485:2003

On November 16, 2015, MindChild Medical, Inc. announced 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

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 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.

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 Fetal Monitoring System

MERIDIAN is a fetal monitoring system that non-invasively measures and displays fetal heart rate (FHR) maternal heart rate (MHR), and uterine contractions/activity (UA). MERIDIAN acquires and displays the FHR, MHR and UA tracing from abdominal surface electrodes that detect the fetal ECG signal, maternal ECG signal, and uterine muscle contraction signal. MERIDIAN is designed for women who are at term (≥ 37 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%[1] of the 4,000,000[2] 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[3]. 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[4]. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US[5], representing an investment of over $700,000,000[6]. MERIDIAN has been developed to provide uninterruptible fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

About MindChild Medical, Inc.

MindChild Medical, Inc., is a privately funded medical device company founded in 2008. MindChild's principal technology platform, the MERIDIAN non-invasive fetal electrocardiograph (fECG) monitor, is designed to report fetal heart rate data equivalent to the gold standard fetal scalp electrode in addition to novel ECG metrics intended to provide obstetricians a deeper understanding of fetal/maternal health and management.

MindChild was co-founded by Adam Wolfberg, MD, Assistant Professor, Tufts Medical Center, Gari Clifford, PhD, previously Principal Research Scientist at Harvard-MIT Division of Health and Science Technology (currently on the faculty at the University of Oxford in the Department of Engineering Science), James Robertson, President and CEO, and Jay Ward, Executive Vice President, both of E-TROLZ, Inc. MindChild has exclusively licensed intellectual property from the Massachusetts Institute of Technology, Tufts Medical Center and E-TROLZ, Inc., a Massachusetts technology company that develops and commercializes breakthrough physiologic monitoring platforms for a wide variety of applications.

For more information, please visit www.mindchild.com.

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

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

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

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

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

[6] Company estimates.