

**FOR IMMEDIATE RELEASE - September 25, 2012**

**MindChild Medical, Inc. Announces Clearance of a 510(k) Pre-Marketing Notification with the US Food and Drug Administration (FDA) for the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor**

**MERIDIAN Provides Continuous Non-Invasive Fetal Heart Rate Readings Using Surface Electrodes That Detect Fetal ECG (fECG)**

(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™ non-invasive fetal heart monitor. MindChild anticipates entering the US market with MERIDIAN now that it has received the FDA clearance. Additional pre-market regulatory filings are anticipated during 2012 and 2013.

“We are thrilled to have reached this milestone”, stated Bill Edelman, CEO. He continued, “MERIDIAN is the first 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 and fetal ECG. 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.”

Thomas Garite, M.D.<sup>1</sup>, Director of Research and Education for the Obstetrix Medical Group, and Editor-In-Chief of the American Journal of Obstetricians and Gynecology, commented, “I am excited to note the FDA pre-market clearance of MERIDIAN. Accurate acquisition of the fetal heart rate signal is critical to the safe practice of obstetrics. Chronic increases in maternal obesity/Body-Mass-Index have created new challenges for existing non-invasive fetal heart rate monitoring technologies. This technology cannot help but to improve our ability to make patient decisions. MindChild's Meridian non-invasive fetal monitoring technology may hold the promise of such an advance.”

**Previous Announcements**

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.

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<sup>1</sup> Thomas Garite, M.D., is a member of the MindChild Clinical Advisory Board



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 Non-Invasive Fetal Heart Rate Monitor**

MERIDIAN is a fetal monitor that non-invasively measures and displays fetal heart rate (FHR). MERIDIAN acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). MERIDIAN may also be used to measure and display fetal heart rate using direct ECG (DECG) with a Fetal Scalp Electrode (FSE). MERIDIAN 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%<sup>2</sup> of the 4,000,000<sup>3</sup> 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<sup>4</sup>. 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<sup>5</sup>. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US<sup>6</sup>, representing an investment of over \$700,000,000<sup>7</sup>. MERIDIAN has been developed to provide uninterrupted 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

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<sup>2</sup> "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

<sup>3</sup> [http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59\\_03.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf)

<sup>4</sup> Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

<sup>5</sup> American Family Physician, 1992 Feb;45(2):579-82

<sup>6</sup> <http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html>

<sup>7</sup> Company estimates.



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](http://www.mindchild.com).

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