

FOR IMMEDIATE RELEASE – April 19, 2015

MindChild Medical, Inc. Announces 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

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 a 510(k) Pre-Marketing Notification Application from the US Food and Drug Administration (FDA) for its MERIDIAN Model M100 non-invasive Fetal Heart Monitor^{1,2}. MindChild anticipates entering the US market with MERIDIAN following the FDA pre-market clearance. Additional pre-market regulatory filings are anticipated during 2015. The Meridian M100 Fetal Heart Monitor³ is intended to be compatible with existing fetal monitoring systems, facilitating rapid adoption by clinicians where MERIDIAN is commercially available. The Meridian M100 Fetal Heart Monitor is designed for women who are at term (> 36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

Previous Announcements

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.

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 is supplied with single-use proprietary electrodes designed to monitor fetal heart rate



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.

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 M100 Non-Invasive Fetal Heart Rate Monitor

The MindChild Medical Meridian M100 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%⁴ of the 4,000,000⁵ 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 movement⁶. 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 infection⁷. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁸, representing an investment of over \$700,000,000⁹. MERIDIAN has been developed to provide uninterrupted fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

⁴ "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

⁵ http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf

⁶ Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

⁷ American Family Physician, 1992 Feb;45(2):579-82

⁸ <http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html>

⁹ Company estimates.



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, previously Assistant Professor, Tufts Medical Center (currently an associate at Boston Maternal-Fetal Medicine), Gari Clifford, PhD, previously Principal Research Scientist at Harvard-MIT Division of Health and Science Technology (currently Associate Professor, Biomedical Informatics (Emory University) and Associate Professor, Biomedical Engineering (Georgia Institute of Technology)), 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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