

FOR IMMEDIATE RELEASE – January 16, 2017

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 4,000,000² 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 movement³. 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 infection⁴. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁵, representing an investment of over \$700,000,000⁶. 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 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.

Press Contact

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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.

FOR IMMEDIATE RELEASE – December 7, 2015 MindChild Medical, Inc. Announces Award of Certificate of Registration by BSI Group America Inc., Under the International Organization for Standardization (ISO) 13485:2003 for the Design, Development and Manufacturing of the MERIDIAN™ Line of Non-Invasive Fetal 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 received ISO 13485:2003 certification for the design, development and manufacturing of its MERIDIAN family of non-invasive Fetal Monitors^{1,2,3,4}. ISO 13485:2003 certification precedes European pre-market submission of a Technical File submission⁵, enabling European commercialization of the MERIDIAN family of Fetal Monitors. 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 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.

The Meridian M100 and M110 Fetal Heart Monitors⁶ 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.

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 MindChild announced November 16, 2015 filing a 510(k) pre-market notification with the US Food and Drug Administration (FDA) for its MERIDIAN Model M110 non-invasive Fetal Heart Monitor

⁵ European pre-market clearance requires the Conformité Européenne, or "European Conformity" ("CE") registration process.

⁶ MERIDIAN is supplied with single-use proprietary electrodes designed to monitor fetal heart rate.

Previous Announcements

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

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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.

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%⁷ of the 4,000,000⁸ 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 movement⁹. 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 infection¹⁰. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US¹¹, representing an investment of over \$700,000,000¹². MERIDIAN has been developed to provide uninterrupted fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

⁷ "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

⁸ http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf

⁹ Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

¹⁰ American Family Physician, 1992 Feb;45(2):579-82

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¹² Company estimates.

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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, MPH⁴, 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.”

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 Monitors⁵ 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

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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 4,000,000⁷ 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 movement⁸. 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 infection⁹. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US¹⁰, representing an investment of over \$700,000,000¹¹. MERIDIAN has been developed to provide uninterrupted fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

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

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

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

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¹¹ Company estimates.

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

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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 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.

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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.

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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.

Press Contact

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FOR IMMEDIATE RELEASE – April 8, 2014

MindChild Medical, Inc. Announces the 1,000th Successful Non-Invasive Fetal Heart Monitoring Session Utilizing the MERIDIAN Fetal Heart 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 the MERIDIAN Non-Invasive Fetal Heart Rate Monitor successfully completed its 1,000th non-invasive fetal heart monitoring session. Five separate health care facilities utilized the MERIDIAN technology to monitor fetal heart rate.

Adam Wolfberg, M.D., Chief Medical Officer for MindChild commented, “We are thrilled to have reached this milestone. Current techniques employed in fetal heart monitoring are limited by a variety of factors. MERIDIAN is intended to provide non-invasive fetal heart measurements similar to those monitored with an invasive Fetal Scalp Electrode (FSE).” Dr. Wolfberg continued, “The average age of our study population was 29.7 ± 6.1 years (ranging from 18 to 48 years old), with Body-Mass-Index (BMI) of 33.7 ± 7.5 (ranging from 18 to 60 BMI) and gestational week at the time of monitoring of 38.1 ± 2.6 . Our population consisted of 16.8% African American, 5% Asian, 14.3% Hispanic, and 64% White Non-Hispanic. We look forward to introducing MERIDIAN to labor and delivery units nationally later this year.”

Participants in the MERIDIAN evaluation included Sangithan Jules Moodley, MD, (Cleveland Clinic, Cleveland, OH), Timothy E. Drake, MD (Summa Akron City and St. Thomas Hospitals, Akron, OH), Julian Robinson, MD, (Newton Wellesley Hospital, Newton, MA), Michael House, MD, (Tufts New England Medical Center, Boston, MA), and James Greenberg, MD (Brigham and Women’s Hospital, Boston, MA).

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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%¹ of the 4,000,000² 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 movement³. 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 infection⁴. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁵, representing an investment of over \$700,000,000⁶. 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

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(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.

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

Press Contact

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FOR IMMEDIATE RELEASE – May 1, 2013

MindChild Medical, Inc. To Present the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 61st Annual Meeting for the American College of Obstetricians and Gynecologists (ACOG) to be Held May 4-8, 2013 in New Orleans, LA

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

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. will present the MERIDIAN™ non-invasive fetal heart monitor at the 61st Annual Meeting for the American College of Obstetricians and Gynecologists (ACOG) to be Held May 4-8, 2013 at the Ernest N. Morial Convention Center, New Orleans, LA, booth 2100.

Adam Wolfberg, M.D., Chief Medical Officer for MindChild stated, “The American College of Obstetricians and Gynecologists is a premier clinical congress, bringing together clinicians and industry, focusing on the needs of the obstetric community. Now that we have received 510(k) pre-marketing notification clearance from FDA for MERIDIAN, we look forward to introducing MERIDIAN to the obstetric community.”

Previous Announcements

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™ Non-Invasive Fetal Heart Rate Monitor.

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About the Fetal Heart Monitoring Market

Over 85%¹ of the 4,000,000² 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 movement³. 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 infection⁴. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁵, representing an investment of over \$700,000,000⁶. 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 The American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (The College), a 501(c)(3) organization, is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit membership organization of approximately 56,000 members, The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. The American Congress of Obstetricians and Gynecologists (ACOG), a 501(c)(6) organization, is its companion organization. www.acog.org.

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FOR IMMEDIATE RELEASE – February 4, 2013

MindChild Medical, Inc. To Present the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 33rd Annual Meeting for the Society for Maternal Fetal Medicine (SMFM) to be Held February 13-15, 2013 in San Francisco, CA

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

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. will present the MERIDIAN™ non-invasive fetal heart monitor at the 33rd Annual Meeting for the Society for Maternal Fetal Medicine (SMFM) to be Held February 13-15, 2013 at the Hilton Hotel, San Francisco, CA, booth 602.

Adam Wolfberg, M.D., Chief Medical Officer for MindChild stated, “The Society for Maternal Fetal Medicine is the premier meeting, bringing together clinicians and industry, focusing on the needs of the obstetric community. Now that we have received 510(k) pre-marketing notification clearance from FDA for MERIDIAN, we look forward to introducing MERIDIAN to the obstetric community.”

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About the Fetal Heart Monitoring Market

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About the Society for Maternal-Fetal Medicine

The Society for Maternal-Fetal Medicine was established in 1977 and is the membership organization for obstetricians/gynecologists who have additional formal education and training in Maternal-Fetal medicine. There are currently about two thousand active members of the Society. The Society hosts an annual scientific meeting in which new ideas and research in the area of Maternal-Fetal Medicine are presented and there are additional frequent Continuing Medical Education courses provided by our members throughout the world. The Society is also an advocate for improving public policy and expanding research funding and opportunities in the area of maternal-fetal medicine.

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FOR IMMEDIATE RELEASE

MindChild Medical, Inc., and The University of Oxford Announces 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 Monitor¹

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

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc., and The University of Oxford today announced the signing of a Sponsored Research Agreement for the development of innovative signal processing algorithms for use with the MERIDIAN™ non-invasive fetal heart monitor. MindChild previously announced clearance for its Pre-Marketing Notification (510(k)) from the US Food and Drug Administration (FDA) for the 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 2013.

The Sponsored Research Agreement will be managed by Gari Clifford, PhD². Dr. Clifford is a member of the faculty at the University of Oxford in the Department of Engineering Science where Dr. Clifford is a University Lecturer and runs the Intelligent Patient Monitoring Group at the Institute of Biomedical Engineering (IBME), University of Oxford. Dr. Clifford is also the Director of the Centre for Doctoral Training in Healthcare Innovation, a major UK government funded centre for teaching translational biomedical engineering. Previously, Dr. Clifford held the position of Principal Research Scientist in the Laboratory for Computational Physiology at the Harvard-MIT Division of Health Sciences. Dr. Clifford received his PhD in Neural Networks and Biomedical Engineering from Oxford University.

Dr. Clifford commented, “I have spent the majority of my academic career developing innovative signal processing approaches which lend themselves to fetal and maternal monitoring. Having participated in the development of the MERIDIAN software design, I am gratified to continue the evolution of this important clinical technology under the auspices of Oxford.” Dr. Clifford continued, “The Sponsored Research Agreement will enable my group to continue the collaboration between industry and academia, which began at MIT. I look forward to advancing the capabilities of MERIDIAN technology following the recent FDA pre-market clearance.”

“We are thrilled to have initiated this important collaboration with Oxford”, 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

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About the Fetal Heart Monitoring Market

Over 85%³ of the 4,000,000⁴ 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 movement⁵. 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 infection⁶. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁷, representing an investment of over \$700,000,000⁸. MERIDIAN has been developed to provide uninterrupted fECG data while

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About the Institute of Biomedical Engineering (IBME), University of Oxford

The Institute of Biomedical Engineering (IBME) is a research institute of the Department of Engineering Science located on the University's medical campus in Headington adjacent to the Churchill Hospital (about a mile from the City centre). Opened in April 2008, the IBME offers a world-class venue for engineers and clinicians to work together on addressing unmet needs in the prevention, early diagnosis and treatment of major diseases. The Institute's core mission is to develop novel medical devices, technology and systems capable of delivering substantial healthcare benefit. Research at the IBME covers patient monitoring, heart disease, stroke, cancer, organ transplantation, regenerative medicine, management of chronic disease, orthopedic engineering and drug delivery systems. More information about the Institute and its research programs may be found at <http://www.ibme.ox.ac.uk>.

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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.¹, 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

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About the Fetal Heart Monitoring Market

Over 85%² of the 4,000,000³ 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 movement⁴. 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 infection⁵. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US⁶, representing an investment of over \$700,000,000⁷. MERIDIAN has been developed to provide uninterrupted fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

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About the Institute of Biomedical Engineering (IBME), University of Oxford

The Institute of Biomedical Engineering (IBME) is a research institute of the Department of Engineering Science located on the University's medical campus in Headington adjacent to the Churchill Hospital (about a mile from the City centre). Opened in April 2008, the IBME offers a world-class venue for engineers and clinicians to work together on addressing unmet needs in the prevention, early diagnosis and treatment of major diseases. The Institute's core mission is to develop novel medical devices, technology and systems capable of delivering substantial healthcare benefit. Research at the IBME covers patient monitoring, heart disease, stroke, cancer, organ transplantation, regenerative medicine, management of chronic disease, orthopedic engineering and drug delivery systems. More information about the Institute and its research programs may be found at <http://www.ibme.ox.ac.uk>.

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FOR IMMEDIATE RELEASE – February 6, 2012

MindChild Medical, Inc. Announces 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

MERIDIAN is intended to Provide Continuous Non-Invasive Fetal Heart Rate Readings Equivalent to the Gold Standard Fetal Scalp Electrode

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“We are excited 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

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FOR IMMEDIATE RELEASE - February 22, 2012

**MindChild Medical, Inc. Announces Formation of a Clinical Advisory Board
for the MERIDIAN™ Line of
Non-Invasive Fetal Heart Rate Monitors**

**The MindChild Clinical Advisory Board Will Advise on the Continued Development of the
MERIDIAN™ Line of Non-Invasive Fetal Heart Rate Monitors**

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced formation of a Clinical Advisory Board (CAB) for its MERIDIAN non-invasive fetal heart monitor. The CAB will meet periodically to assess the development strategies for the Meridian Monitor and advise the company on the state of the fetal monitoring market. Adam Wolfberg, MD, currently Chief Medical Officer for MindChild, will assume the position of Chairman of the CAB immediately.

Dr. Wolfberg commented, "Formation of the Clinical Advisory Board is an important milestone in the development of the MERIDIAN system. The world-class clinical capabilities and real-life experiences represented by this Clinical Advisory Board in fetal monitoring make this group uniquely suited to support the ongoing development of MindChild's non-invasive fetal monitoring technology."

Joining the Clinical Advisory Board are:

Aaron B Caughey, MD, PhD, is the Chair of the Department of Obstetrics and Gynecology and Director of the Oregon Health Sciences University Center for Women's Health. He is nationally recognized as a dedicated clinician, accomplished educator, and prolific researcher.

Emily F. Hamilton, MDCM, is the senior vice president of clinical research at PeriGen, and is Adjunct Professor of Obstetrics and Gynecology at McGill University. Dr. Hamilton presents regularly at academic conferences focusing on patient safety or risk management for obstetrical services.

Gary Hankins, MD, is the Jennie Sealy Smith Distinguished Professor and Chairman, University of Texas Medical Branch, Department of Obstetrics and Gynecology.

Michelle L. Murray, PhD, RNC-OB, is the founder and President of Learning Resources International, Inc. which has produced and provided continuing education courses, educational products, and texts for nurses related to fetal monitoring and labor and delivery nursing since 1986. She is a clinical Associate Professor of Nursing at the University of New Mexico and a full-time member of the Nursing Program faculty at Central NM Community College.



Michael Ross, MD, MPH, 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).

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