FDA Breakthrough Device Designation granted to Keeping Labor Safe's Fetal Reserve Index (FRI)

Built on four decades of maternal-fetal medicine by Professor Mark Evans, the Singapore company's platform targets one of the most consequential, and least modernized, moments in medicine: the hours of labor.

SINGAPORE, October 20, 2026. More than 130 million babies are born worldwide every year, 3.6 million of them in the United States. Medicine can now sequence a genome in hours and operate through robotic arms, yet the clinicians watching over labor still rely largely on fetal heart-rate monitoring introduced half a century ago, whose tracings experienced specialists often read differently. What happens in those hours can shape the rest of a child's life.

Keeping Labor Safe Pte. Ltd. (KLS), a Singapore-headquartered maternal, fetal and neonatal health technology company, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to its Fetal Reserve Index (FRI) and its proposed indication for use. FDA's Center for Devices and Radiological Health issued the designation in a letter dated October 19, 2026.

FDA reserves the coveted Breakthrough Device Designation for technologies that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions. It gives KLS direct, interactive engagement with FDA experts during development and prioritized review of future submissions, a faster and more collaborative route toward the U.S. market.

FRI is the product of a scientific and medical career spanning over four decades . Professor Mark I. Evans, MD, co-founder and Chief Medical Officer of KLS, is Clinical Professor of Obstetrics, Gynecology and Reproductive Science at the Icahn School of Medicine at Mount Sinai in New York and a Visiting Professor at the National University of Singapore. In 2023 the International Society for Prenatal Diagnosis named him a Pioneer in Prenatal Diagnosis and Therapy, recognizing work that helped define modern prenatal diagnosis and fetal therapy. For years he and his colleagues pursued one question: how to read fetal monitoring in the context of each mother, each baby and each labor. The answer has produced more than 20 publications, including 19 peer-reviewed journal articles, and patents granted in the United States, Europe, China, Japan, Israel and Brazil. Pivotal clinical studies are now being planned with partners in the United States and Singapore.

Devanathan Raghunathan PhD, co-founder and Chief Executive Officer, is turning that science into a scalable global company. A scientist by training, with research at the Max Planck Institute, A*STAR and MIT, he has worked across healthcare consulting, corporate finance, M&A, venture capital and healthcare innovation.

> *"The cost of uncertainty at birth is carried for a lifetime – by children, by families, and by health systems. Our task is to turn decades of clinical science into software that labor wards can adopt, test it rigorously, and make it available wherever babies are born, including health systems where specialist care is scarce. Breakthrough designation gives us closer engagement with the FDA while we generate that evidence. Because ultimately, our success will not be measured by the technology we develop, but by the futures we help protect."*
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> **Devanathan Raghunathan PhD, Co-founder and CEO, Keeping Labor Safe**

The designation lands as the United States moves decisively on childbirth. In June 2026, the Advanced Research Projects Agency for Health (ARPA-H) launched Making Obstetrics Care Smart (MOCS), a four-year, $90.7 million program to bring next-generation fetal monitoring and decision tools to labor and delivery. ARPA-H estimates that 134,000 term babies are born each year with severe hypoxia, that about 83,000 cesarean deliveries a year are unnecessary, and that fetal monitoring is a factor in 45% of obstetric litigation cases. Coincidentally, on the same day as FDA's letter to KLS, the White House announced a new Women's Health Division at the National

Institutes of Health, with maternal health among its priorities. KLS is not part of these programs yet, but it shares their goal, and it arrives with a designated device.

KLS joins a select group of companies to receive Breakthrough Device Designation in labor monitoring. Raydiant Oximetry holds the designation for fetal pulse oximetry and began an early feasibility study under an FDA Investigational Device Exemption in 2024. Australia's VitalTrace holds it for DelivAssure, a sensor that measures fetal lactate continuously during labor. Both approaches add new sensors. In contrast, KLS is software-first, designed to work with the fetal monitoring equipment hospitals already own, which allows it to scale across health systems without new hardware.

The designated device is the first step in a larger plan. KLS is building a neuroprotection platform that spans pregnancy, labor and the first hours of life, for hospitals, clinics and homes, including places where specialist support is far away. With Breakthrough designation in hand, the company is moving to pivotal evidence, international clinical partnerships and its first regulatory submissions.

"A child may spend only a few hours being born, and will live a lifetime with what happens in those hours. After more than forty years in maternal-fetal medicine, I still feel the weight of that. We owe every child a safe birth, and with it the best possible chance at everything that comes after."

Professor Mark I. Evans, MD, Co-founder and Chief Medical Officer, Keeping Labor Safe

ABOUT KEEPING LABOR SAFE

Keeping Labor Safe Pte. Ltd. is a Singapore-headquartered medical technology company developing clinical decision-support software for care during labor and the first hours of life. Its portfolio includes the Fetal Reserve Index (FRI) and the SHARA Score. KLS was co-founded by Professor Mark I. Evans, MD, and Devanathan Raghunathan PhD. Saving brains. Shaping futures. www.keepinglaborsafe.com

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