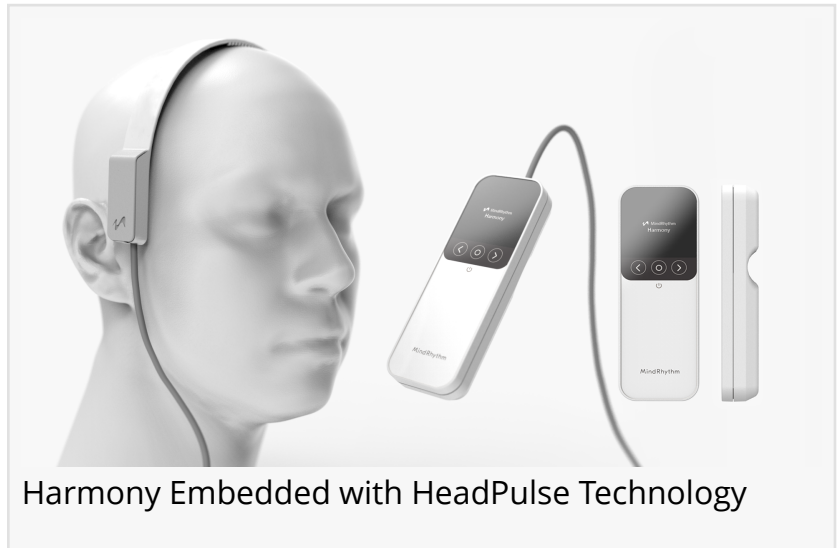


# MindRhythm's Innovative Device for LVO Stroke Granted Breakthrough Designation by the FDA

CUPERTINO, CALIFORNIA, UNITED STATES, October 30, 2023

/EINPresswire.com/ -- [MindRhythm Incorporated](https://www.mindrhythm.com/), a neurodiagnostic technology company based out of Cupertino, California, today announces the FDA has awarded a Breakthrough Device Designation for its Harmony headset embedded with HeadPulse technology. The function of MindRhythm's Harmony device is to aid in the assessment of suspected stroke patients in the prehospital setting to determine whether the patient may have a large vessel occlusion (LVO) stroke. LVO strokes are among the most debilitating types of strokes.



The FDA describes the Breakthrough Devices Program as “a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.” The program considers the potential for accessibility of a device to make a clinically meaningful impact as well as the risks and benefits compared to standard of care. Breakthrough designation allows the FDA to provide prioritized interaction and review of manufacturer’s submissions.

MindRhythm chose to pursue breakthrough designation in advance of its submission for FDA clearance with the belief that Harmony meets all primary and secondary criteria for the program, chief among them: device availability is in the best interest of patients. There is currently no device available that can easily and accurately identify LVO before a patient arrives at a hospital. Harmony is designed to help EMS professionals determine the presence or absence of LVO stroke. This information can be used by EMS to transport patients to the closest hospital that can deliver the most appropriate level of skilled care for their stroke type.

“Time to treatment is absolutely critical for favorable outcomes in all strokes. Excellent treatments are available for stroke patients, but the technology to treat large vessel strokes is

only available at select hospitals. Proper stroke type identification and transport can shorten time to treatment. With the breakthrough designation, the FDA is recognizing the potential for improving outcomes with this patient group” stated CEO John Keane.

Dr. Wade Smith MD, PhD, of University of California San Francisco shared, “This designation highlights the position that Harmony is truly breakthrough as it acknowledges the importance of this product for our patients and the likelihood that MindRhythm’s pivotal trial will be successful. We appreciate the high standards the FDA requires as it adds confidence to medical professionals that the use of the device is in the best interests of our stroke patients.”

#### About the Harmony Headset

Harmony is a novel, noninvasive medical device designed to aid in the rapid identification of Large Vessel Occlusion (LVO) strokes, the most debilitating of all stroke types. Harmony monitors a newly discovered physiology MindRhythm calls the “HeadPulse.” The HeadPulse is measured by applying a highly sophisticated sensor to the patient’s head, measuring minute pulsations produced by each heartbeat. The HeadPulse changes dramatically during LVO strokes, which is read by Harmony. Coupling the Harmony results with a simple clinical examination of stroke, the device can discriminate LVO strokes among stroke patients in a matter of seconds.

#### About MindRhythm

MindRhythm is a medical technology company focused on preventing neurological injury. Founded by world-renowned scientific experts with significant commercialization success, MindRhythm’s monitoring technologies provide real-time visibility to life-threatening situations at home, prehospital, in the operating room, and on the field. MindRhythm’s technologies allow clinicians to intervene, optimize and manage care to prevent brain damage. Collaborating with the healthcare community, MindRhythm looks to apply a systematic approach to reducing time to treatment in strokes and monitor neurological health during recovery from concussion.

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