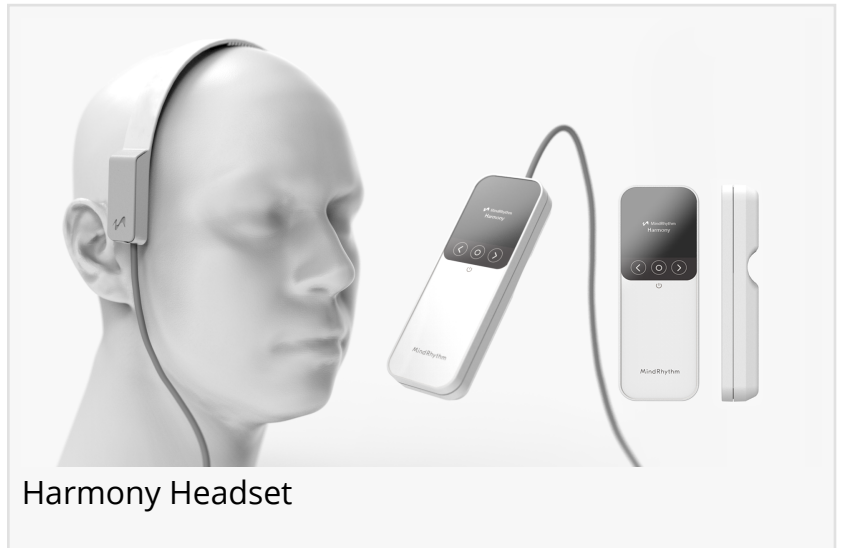


MindRhythm's Harmony for Prehospital Large Vessel Occlusion Stroke Identification Submitted for FDA Clearance

CUPERTINO, CA, UNITED STATES, October 1, 2025 /EINPresswire.com/ -- MindRhythm Incorporated, a neurodiagnostic company based out of Cupertino, California, today announces it has officially submitted a de novo application to the U.S. Food and Drug Administration (FDA) seeking clearance for its Harmony device designed for prehospital large vessel occlusion (LVO) stroke identification.



Harmony Headset

MindRhythm's novel, noninvasive Harmony device was developed to address the limitations of prehospital stroke identification in a simple and efficient way. MindRhythm's Harmony headset, embedded with HeadPulse biometric analysis technology was submitted as an "...aid in the assessment of suspected stroke to determine whether a patient may be experiencing large vessel occlusion stroke."

“

This is a significant milestone for MindRhythm and stroke care.

MindRhythm's ultimate objective is to improve outcomes in this life-threatening condition.”

John Keane, MindRhythm CEO

Accurate prehospital stroke identification is critical due to the limited availability of stroke treatment facilities. Today, the majority of stroke affected patients are transported to the closest hospital which may not be able to treat their condition often delaying critical care. LVO patients need to be transported to a thrombectomy capable center while all other stroke patients can be transported to the closest stroke center. Using Harmony's rapid “LVO Y/N” information, EMS professionals can confidently triage LVO patients to thrombectomy centers and send non LVO

patients to the closest stroke center expediting access to critical treatment for all stroke patients.

MindRhythm CEO, John Keane commented: “This is a significant milestone for MindRhythm and

stroke care. The addition of Harmony's objective biometric data to a clinical assessment allows EMS professionals to more effectively triage stroke patients with the goal of expediting time to treatment. MindRhythm's ultimate objective is to improve outcomes in this life-threatening condition."

This de novo submission follows two previous achievements for MindRhythm: Harmony's Breakthrough Device Designation in 2023 and a successful completion of one of the largest prehospital studies of a stroke identification device ever conducted - EPISODE (hEadPulse for Ischemic StrOke DEtection Prehospital). Based on these accomplishments and EMS feedback, MindRhythm anticipates broad adoption when Harmony is available following FDA clearance.

About the Harmony Headset

Harmony is a novel, noninvasive diagnostic medical device that can rapidly identify patients with Large Vessel Occlusion (LVO) strokes, the most debilitating of all stroke types. Harmony monitors a biometric discovered by MindRhythm that it 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 the device can discriminate LVO strokes among Code 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 technology provides real-time visibility to life-threatening situations at home, prehospital, in the operating room, and on the field. MindRhythm's technology allows 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 injury. Together, let's save lives and improve the quality of life: <https://mindrhythm.com>

Beth Johnson

MindRhythm Incorporated

+1 860-836-8630

[email us here](#)

Visit us on social media:

[LinkedIn](#)

[Instagram](#)

[Facebook](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/854292571>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors

try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2025 Newsmatics Inc. All Right Reserved.