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# Noah Labs Obtains FDA Breakthrough Device Designation for its AI-Powered Voice Diagnostic for Heart Failure

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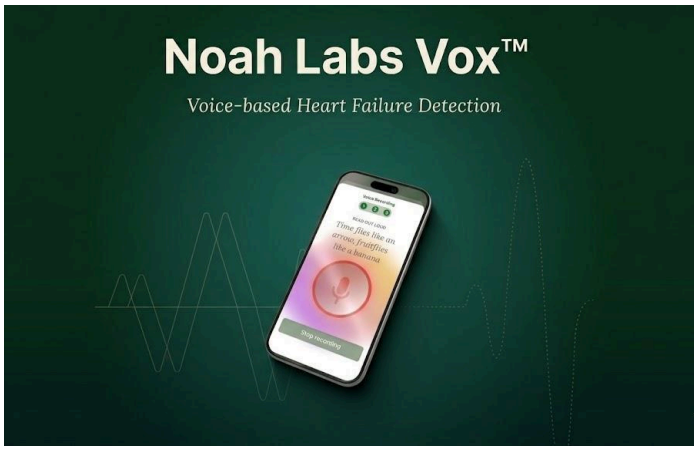


US FDA Breakthrough Device Designation granted for Noah Labs Vox™, voice-based algorithm for early detection of worsening heart failure. **Image Credit: Noah Labs**

*Noah Labs Vox™ is an AI-based software-only medical device, which detects worsening heart failure using proprietary vocal biomarkers, up to three weeks before hospitalization.*

*Noah Labs Vox™ complements the company's existing commercialized Noah Labs Ark™ remote monitoring platform for heart failure management.*

**BOSTON, Massachusetts, March 25, 2026**. Noah Labs' Noah Labs Vox™, a voice-based algorithm that detects worsening heart failure weeks before hospitalization, has received US Food and Drug Administration (FDA) Breakthrough Device Designation (BDD).

This recognition expedites Noah Labs' upcoming clearance and commercial activities, including the company's upcoming FDA trial set to kick off shortly. Noah Labs Vox™ uses a proprietary machine learning algorithm to analyze subtle vocal changes, enabling non-invasive, scalable remote monitoring for heart failure patients. With just a 5-second daily voice clip, the technology enables early intervention, reduces readmissions, and improves outcomes – accessible even in rural and resource-limited settings.

Noah Labs Vox™ is built on the world's largest exclusive dataset of heart failure patient voice recordings, with more than three million voice samples to date. The software-only medical device has been validated across more than five multicentre clinical trials. In collaboration with Mayo Clinic, UCSF, Charité Berlin, Maastricht University Medical Center, and Hospital Clínic de

Barcelona, the algorithm has demonstrated exceptional sensitivity in detecting worsening heart failure.

> *"Voice is a powerful predictor for worsening heart failure. This Breakthrough Device Designation is a pivotal milestone in Noah Labs Vox™'s path to driving early access to life-saving interventions for patients with life-threatening diseases."*
>
> *— Oliver Piepenstock, CEO & Co-Founder, Noah Labs*

> *"The FDA Breakthrough Device Designation for Noah Labs Vox™ is a significant achievement for heart failure care. Early detection of clinical worsening is a central challenge in managing these patients — the ability to identify deterioration weeks before hospitalization, using nothing more than a patient's voice, has the potential to fundamentally change how we intervene and prevent adverse outcomes."*
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> *— Prof. Felix Hohendanner, MD, PhD, Charité Berlin*

Heart failure is the leading cause of hospitalization among adults worldwide, with more than one million admissions annually in the United States alone. Current monitoring approaches are invasive, costly, or dependent on in-person care — leaving the majority of the 64 million patients globally without reliable early warning systems.

Noah Labs Vox™ addresses this gap with a single 5-second daily voice recording and no hardware required. The breakthrough technology detects deterioration weeks before a hospitalization event, enabling clinicians to intervene to prevent further clinical worsening.

**About Noah Labs**

Noah Labs is a Boston and Berlin-based healthcare technology company dedicated to empowering heart failure patients to live longer, healthier lives by providing the most powerful remote patient monitoring & management globally. Founded in 2021, by Oliver Piepenstock, Marcus Hott, and Dr. Leonhard Riehle, its portfolio includes Noah Labs Ark™, a CE-marked remote monitoring platform deployed across European clinical sites. Noah Labs Vox™ has been clinically validated in partnership with Mayo Clinic, UCSF, Charité Berlin, Maastricht University Medical Center, and Hospital Clínic de Barcelona. The company is also a member of the American Heart Associations Centre for Health Technology & Innovation and an alumnus of the Google for Startups AI Academy. Noah Labs has received grant funding from the European Innovation Council (EIC) Accelerator. Noah Labs has attracted a combined total of $12 million in public grant and private equity funding. For more information, visit www.noah-labs.com.

**About the FDA Breakthrough Devices Program**

The FDA Breakthrough Devices Program is designed to provide patients and healthcare providers with timely access to novel medical devices by expediting their development, assessment, and review. To qualify, a device must offer the potential for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The program accelerates FDA review of premarket approval applications, 510(k) clearances, and De Novo marketing authorizations for qualifying devices, while maintaining the rigorous evidentiary standards required for market authorization. For more information, visit www.fda.gov.