

## CardioRenal receives FDA Breakthrough Device Designation for TENOR

Breakthrough Device status will help advance the world's first connected device to remotely monitor blood potassium levels in patients with severe chronic kidney disease

**Grenoble, France, May 31, 2023** – CardioRenal, a pioneer in the remote treatment of patients with severe chronic kidney disease (CKD), today announces that its TENOR device has obtained Breakthrough Device Designation from the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA).

CardioRenal developed [TENOR](#), a connected medical device that combines multiple innovative technologies to assist patients with chronic illnesses, including CKD, in measuring their blood potassium levels at home. Patients will collect blood for testing at home using Tasso+™, a convenient, easy-to-use, virtually pain-free blood collection device with FDA 510(k) Class II medical device clearance. Doctors can then remotely access the measured data, enabling them to effectively control and normalize patient potassium levels.

“This designation is a tremendous recognition by the FDA of our R&D excellence. It will boost our efforts in bringing the TENOR device to the millions of patients who need it,” said Maurice Bérenger, CEO of CardioRenal. “We look forward to working closely with the FDA to start our clinical trials later this year.”

To qualify for this status, the equipment must feature breakthrough technologies, there must be no FDA-approved or cleared alternatives to the device, it must have significant advantages over existing approved or cleared alternatives, or its application must serve the best interests of patients.

“People are increasingly calling for at-home health solutions, and the partnership with CardioRenal is an exciting opportunity to again demonstrate the benefits to patient care,” said Ben Casavant, PhD, CEO and co-founder of Tasso, Inc., which makes the Tasso+ device. “We look forward to demonstrating that our blood collection device can be used in combination with the TENOR system to obtain a blood sample in a way that is convenient, addresses patient needs and meets FDA standards for potassium analysis. This fits perfectly in our mission to combine clinical excellence and patient-centric solutions.”

The FDA Breakthrough Devices Program helps patients receive timely access to innovative technologies that have the potential to provide more effective diagnosis or treatment for life-threatening or irreversibly debilitating diseases and conditions. As part of this program, the FDA will provide CardioRenal with priority review and interactive communication from its experts and senior managers, to assist the company on its path to commercialization in the US.

[Globally, around 843 million people live with CKD](#). These patients frequently have fluctuating blood potassium levels, which exposes them to possible cardiac complications. These associated cardiovascular events account for up to [30% of deaths in patients with CKD](#).



### About the FDA Breakthrough Devices Program

The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to certain medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

### About Tasso

Tasso is an emerging healthcare technology company that is transforming the traditional blood collection paradigm with a patient-centric approach. The company's devices enable simple, convenient, and virtually painless blood collection for users. Tasso technology has the power to bring healthcare anywhere, any time. Headquartered in Seattle, Washington, Tasso is privately held and funded by grants, investments, and co-development deals with various industry leaders. For more information, please visit [www.tassoinc.com](http://www.tassoinc.com)

### About CardioRenal

CardioRenal's mission is to save CKD patient lives. The company's solution, TENOR, is designed to allow patients to regain ownership of their health and improve their chronic disease management. Its breakthrough hardware technology and its AI based software platform enable doctors to optimize patient treatment through remote monitoring of key blood biomarkers.

[www.cardio-renal.com](http://www.cardio-renal.com)

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*Precision medicine for Chronic Kidney Disease and Heart Failure*