

ASX ANNOUNCEMENT

16 September 2026

EBR's FDA plan for addressing echo-induced pacing risks

Key Highlights

- EBR met with FDA to discuss our plan to proactively update our labelling to increase the visibility of echo-induced pacing risk and its mitigations.
- During that meeting, EBR addressed FDA questions and FDA was aligned with the path forward.
- EBR will submit a "Changes the Being Effected" (CBE) PMA Supplement
- The CBE PMA Supplement is a pathway to rapidly implement safety enhancements whilst the supplement is under review
- The submission represents a targeted, proactive effort by EBR to maximise patient safety as the commercial rollout of the WiSE® System continues to scale

Santa Clara, California; 16 September 2026: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, today announces its plan to submit a Changes Being Effected (CBE) Premarket Approval (PMA) supplement to the FDA in Q4 2026.

The upcoming regulatory submission is proactive initiative focused on updating the commercial labelling for the WiSE System. This update is designed to elevate the visibility and prominence of mitigation strategies to prevent known complications within the device labelling.

John McCutcheon, EBR Systems' President & Chief Executive Officer, said:

"As the commercial adoption of the WiSE System gathers momentum across the US, our paramount commitment remains patient safety and procedural success. This proactive labelling update ensures that the clinical mitigations we have developed are clearly visible and top-of-mind for implanters, empowering them to mitigate complication before they occur."

EBR met with FDA to discuss plans to proactively update our labelling to increase the visibility of echo-induced pacing risk and its mitigations. During that meeting, EBR addressed FDA questions and FDA was aligned with the path forward.

The CBE PMA provides a streamlined regulatory pathway for labelling improvements, allowing safety enhancements to be implemented without requiring prior FDA approval.

The Company is pleased with the collaborative FDA interaction and is aligned with FDA on ensuring patient safety.

ENDS

This announcement has been authorised for release by the EBR Systems Routine Disclosure Committee, a Committee of the Board of Directors.

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About EBR Systems

Silicon Valley-based EBR Systems (ASX:EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device in most markets and is currently only available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment in or completion of our clinical trials and our associated regulatory applications and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. These forward-looking statements are based on EBR Systems' current expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's ASX-traded (ASX: EBR) CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.