

EBR provides update on FDA review of cybersecurity incident

Key Highlights

- FDA has reviewed EBR's completed cybersecurity risk assessment following the cybersecurity incident previously disclosed to the ASX on 15 April 2026
- The FDA agreed that no field corrective action or recall relating to the WiSE® System is warranted
- The incident aligns with a Controlled Risk classification under FDA postmarket cybersecurity guidance
- No evidence has been identified of any impact to fielded WiSE CRT System safety or performance
- EBR is continuing cybersecurity remediation and hardening activities through its established quality and regulatory processes

Santa Clara, California; 9 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, provides an update on the cybersecurity incident previously disclosed to the ASX on 15 April 2026.

Following submission of EBR's completed cybersecurity risk assessment, the U.S. Food and Drug Administration (FDA) has reviewed the information provided and agreed that no immediate field corrective action or recall relating to the WiSE System is warranted.

The FDA also advised that the incident aligns with a Controlled Risk classification under Section VI of the FDA's 2016 guidance, *Postmarket Management of Cybersecurity in Medical Devices*.

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

"Patient safety, device integrity and responsible postmarket management remain EBR's highest priorities.

Following submission of EBR's completed cybersecurity risk assessment, the FDA has advised that the incident aligns with a Controlled Risk classification and has agreed with EBR's response.

We continue to focus on best practices for cybersecurity through our established quality and regulatory processes."

As previously announced, EBR became aware of a cybersecurity incident in February 2026. The Company promptly took steps to contain the incident, investigate the potential impact and notify relevant regulatory authorities.

As part of its postmarket cybersecurity review, EBR completed a formal cybersecurity risk assessment with support from independent cybersecurity specialists. The assessment evaluated the potential impact of the incident on the safety and effectiveness of WiSE.

Based on the information reviewed to date, EBR has not identified evidence of any impact to fielded device safety or performance.

EBR has implemented corporate cybersecurity improvements, including strengthened credential management controls, anti-phishing training and enhanced endpoint monitoring.

The Company is also progressing additional product cybersecurity remediation and hardening activities.

EBR will continue to provide progress updates to the FDA as requested and remains committed to maintaining appropriate cybersecurity controls across its systems and products.

For more information about EBR, please visit <https://www.ebrsystemsinc.com/>.

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.