ASX: EIQ RELEASE **15 December 2025**

Formal lodgement of FDA submission for EchoSolv HF

- **Successful lodgement of market clearance application for EchoSolv HF with the US Food & Drug Administration via the 510(k) premarket notification pathway**
- **Submission incorporates results of successful clinical validation study with Mayo Clinic Platform's validation capabilities on an independent dataset of 17,000 individual patient echocardiograms**
- **FDA clearance of EchoSolv HF* unlocks a significant opportunity in the US:**
  - **Only 50% of heart failure cases are accurately diagnosed**
  - **Estimated that 1 in 4 Americans will develop heart failure in their lifetime**
  - **Heart failure is the leading cause of rehospitalisation and accounts for 17% of US healthcare expenditure, underpinning a total addressable market of US$60Bn in the US**

Sydney: AI and Medical Technology Company Echo IQ Limited (ASX: EIQ) ("Echo IQ" or "the Company") is pleased to confirm the formal lodgement of its market clearance application for EchoSolv HF, its heart failure clinical decision support software, via the US Food & Drug Administration's ("FDA") 510(k) premarket notification pathway. The submission incorporates results from a clinical validation study conducted specifically to support the 510(k) application.

The study, designed to validate the model's ability to detect heart failure on an independent dataset, showed EchoSolv HF met the primary endpoint with study data demonstrating sensitivity of 99.5% and specificity of 91.0% in the detection of heart failure across a dataset of 17,000 echocardiograms from Mayo Clinic Platform.

An FDA 510(k) is a premarket submission required for medical devices to demonstrate that they are "substantially equivalent" in safety and effectiveness to a legally marketed device, "predicate device". Once substantial equivalence has been determined and FDA clearance has been issued, the company may market and distribute the device in the United States for the cleared indications for use.

FDA clearance, if obtained, would unlock a significant addressable market opportunity for EchoSolv HF in the US healthcare sector, where heart failure is the leading cause of hospitalisation and accounts for 17% of US healthcare expenditure nationally.

Management commentary:

Chief Executive Officer, Mr Dustin Haines, said: *"We are pleased to have completed the formal submission process for EchoSolv HF via the FDA's 510(k) clearance pathway. The lodgement of the submission is a testament to the hard work and disciplined execution of Echo IQ's operations team alongside our key industry partners including Mayo Clinic."*

"With the submission process complete, we will continue to work with our broad network of industry partners across both product development and distribution, ahead of an expected FDA decision in the coming months. The ongoing advancement of our healthcare technology suite positions the Company for another momentum driven year ahead, leveraging our proprietary technology to deliver improved healthcare solutions, and we look forward to updating our investors on key progress initiatives early in the new year."

- ENDS -

Authorised for release by the Board of Directors of Echo IQ Limited.

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ABOUT ECHO IQ
Echo IQ uses AI-driven technology and proprietary software to improve decision making in Cardiology.
The company is based in Sydney, Australia.

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995:

To the extent any statements in this announcement contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (collectively, the "PSLRA"). This announcement contains forward-looking statements regarding Echo IQ's expectations, intentions, and projections regarding future events, including statements about FDA 510(k) submission timing, potential FDA clearance of EchoSolv HF, commercialisation plans, market opportunities, and expected product performance. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "expect," "estimate," "plan," "will," "would," and similar expressions. These forward-looking statements are based on current expectations and assumptions and are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by such statements.

Key risks and uncertainties include, but are not limited to: the timing and outcome of the FDA 510(k) review process, which is uncertain and may result in delays, requests for additional information, or denial of clearance; regulatory requirements that may change or differ from expectations; the ability to successfully commercialise EchoSolv HF in the US market; market acceptance by healthcare professionals and institutions; competitive factors and the development of alternative technologies; reimbursement policies and healthcare spending trends; and the Company's ability to execute its commercialisation strategy. The Company's ability to achieve the market opportunities described in this announcement is subject to numerous factors beyond its control.

Actual results, performance, or achievements may differ materially from those expressed or implied in forward-looking statements. The forward-looking statements in this announcement are made as of the date hereof, and Echo IQ assumes no obligation to update or revise any forward-looking statements, whether because of new information, future events, or otherwise, except as required by applicable law, including the securities laws of the United States and ASX Listing Rules. Investors are cautioned not to place undue reliance on forward-looking statements. The Company cautions readers that the foregoing list of important factors is not exhaustive and encourages readers to review the detailed risk factors included in the Company's filings with the ASX for a more complete discussion of factors that could affect the Company's future results.