ASX: EIQ RELEASE **19 November 2026**

EchoSolv HF regulatory update

Sydney: AI and Medical Technology Company Echo IQ Limited (ASX: EIQ) ("Echo IQ" or "the Company") advises that the US Food & Drug Administration (FDA) has completed its supervisory review of the Company's appeal of the "not substantially equivalent" (NSE) determination for EchoSolv HF and has upheld that determination. The Company is evaluating its options with its US regulatory and legal advisors. These include engaging with the FDA on the path forward, a new 510(k) submission, and further review available under FDA procedures.

The Company had previously identified a new 510(k) submission as a potential outcome of the review process (refer ASX announcement: 17 September 2026). In parallel with the Company's ongoing engagement with the FDA, Echo IQ has been working extensively with its US regulatory advisors, key opinion leaders and clinical study partners over recent weeks to prepare for a pre-submission meeting and a potential new 510(k) submission.

A potential pathway forward was detailed in the Company's most recent correspondence with the FDA. Through ongoing engagement with the regulator, Echo IQ will seek to confirm with the FDA the analysis and clinical evidence required to address the matters raised in the FDA's determination, and the most appropriate regulatory pathway.

The decision does not affect EchoSolv AS, which remains FDA-cleared and commercially available in the US.

Echo IQ will keep the market informed in accordance with its continuous disclosure obligations.

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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.

Forward-looking statements:
This announcement contains forward-looking statements, including statements about the Company's regulatory options and plans and the timing and outcome of any FDA process. These statements reflect current expectations and are subject to risks and uncertainties, many outside the Company's control, including the outcome of FDA review. Actual results may differ materially. Except as required by law or the ASX Listing Rules, the Company undertakes no obligation to update these statements.

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