ASX: EIQ **8 September 2026**

EchoSolv HF FDA application update

- **Initial EchoSolv HF 510(k) application has not received clearance for commercial use at this time**
- **Company assessing multiple administrative and regulatory options available with the FDA**
- **EIQ remains well funded with cash at bank of over $105m (as at July 2026)**
- **Strong underlying business momentum continues, including growing US uptake of FDA-cleared EchoSolv AS, expanding commercial activities and advancement of broader R&D pipeline**
- **Webinar scheduled for 8:30am (AEST) on Wednesday, 9 September**

Sydney: AI and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX: EIQ) advises that the US Food and Drug Administration ('FDA') has issued a Not Substantially Equivalent ('NSE') determination for the Company's initial EchoSolv HF 510(k) application.

Upon receipt of the FDA's determination, Echo IQ, together with its US regulatory and legal advisors, its study partners, and independent statistical experts, has commenced a detailed review of the regulatory matters raised.

The Company believes there is a pathway forward for clearance under the 510(k) route and intends to engage with the FDA to further clarify the matters identified in the determination and assess all administrative and regulatory options available to Echo IQ. This process will inform the most appropriate and efficient pathway to progress EchoSolv HF towards US regulatory clearance.

Echo IQ remains confident in the clinical rationale underpinning EchoSolv HF and the significant unmet clinical need in the identification of patients with heart failure. The Company intends to continue to progress the EchoSolv HF regulatory program, while maintaining its broader US commercial strategy.

This determination does not impact the FDA-cleared EchoSolv AS platform or its ongoing commercialisation in the US. Echo IQ will continue to advance its US commercial infrastructure, reimbursement pathway, customer pipeline and strategic relationships, providing a platform to support the future commercialisation of EchoSolv HF, subject to obtaining required regulatory clearance.

In parallel, Echo IQ will continue to invest in its broader R&D pipeline, including the development of solutions targeting additional disease states and new clinical modalities. This pipeline remains best-in-class and represents a significant opportunity to extend the EchoSolv platform across cardiovascular care and into new areas of clinical need.

Management commentary:

CEO, Mr Dustin Haines, said: *"While we are disappointed in the decision on our initial application and our view differs on certain aspects, the determination provides us with detailed feedback that we can now assess with our US regulatory and legal advisors and, importantly, discuss directly with the FDA.*

Our immediate priority is to understand the matters raised in full and determine the most efficient pathway forward. We remain confident in the underlying technology, the clinical rationale for EchoSolv HF and the significant opportunity to improve the identification of patients at risk of heart failure.

Echo IQ is approaching this next phase from a position of strength. We have an FDA-cleared product in EchoSolv AS, a growing US presence, important strategic relationships and a strong balance sheet. These foundations remain unchanged and provide us with the resources and infrastructure required to progress the additional work necessary to advance EchoSolv HF towards regulatory clearance."

Investor webinar:

CEO, Mr Dustin Haines, President of the US, Mr Nick Lubbers, and CFO, Mr Matthew Dodds will host a webinar at 8:30am (AEST) on Wednesday, 9 September. The briefing will be followed by a Q&A session. Questions can be submitted to investor@echoiq.ai or henry.jordan@sdir.com.au or during the webinar. Investors can register for the webinar via the following link:

- https://us02web.zoom.us/webinar/register/WN_LUL1CqldRaStHFNVul5Kig#/registration

- 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.