



EchoSolv HF FDA 510(k) update

Sydney: AI and Medical Technology company Echo IQ (“the Company” or “Echo IQ”) (ASX: EIQ) wishes to provide the following update on its EchoSolv HF 510(k) application with the US Food & Drug Administration (“FDA”) (refer ASX announcements: 8 and 17 September 2026).

The Company advises it has filed a request for supervisory review (an administrative appeal) of the FDA’s Not Substantially Equivalent determination for EchoSolv HF. The appeal has been accepted by the regulator and the FDA’s ombudsman has been informed.

A meeting with the FDA in connection with the Company’s appeal is expected to occur within the next 30 days. Following this meeting, Echo IQ anticipates it will have greater clarity on the regulatory pathway forward for EchoSolv HF.

The Company will provide additional updates as developments associated with its regulatory pathway materialise.

- ENDS -

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

Investor Enquiries:

Andrew Grover, Executive Chair

Andrew.grover@echoiq.ai / investor@echoiq.ai

Henry Jordan, Six Degrees Investor Relations

Henry.jordan@sdir.com.au / +61 (0) 431 271 538

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.

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