

ASX ANNOUNCEMENT MARKET RELEASE

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Artrya lodges Q-Submission as a key step to finalise FDA application

Highlights

- **Artrya lodges Q-Submission (Q-Sub) with the FDA as a key step to finalise 510(k) application process**
- **Q-Sub meeting expected within four to six weeks**
- **510(k) application submission to be made following Q-Sub meeting.**

Artrya Limited (ASX:AYA), ('Artrya' or the 'Company'), a medical technology company focused on commercialising its patented AI platform that detects key coronary artery disease imaging markers, has lodged a second Q-Submission (Q-Sub) as a key step in the process to finalise its US Food and Drugs Administration (FDA) application.

A Q-sub is a formal written request from a company for feedback from the FDA to help guide product development and/or application preparation. Artrya expects the Q-Sub to take place within the next four to six weeks.

Artrya successfully conducted the first Q-Sub meeting with the FDA in June 2023, during which a pathway to 510(k) regulatory clearance for the Salix Coronary Anatomy product was determined. A 510(k) is a premarket submission made to the FDA to demonstrate the device to be marketed is as safe and effective, that is, substantially equivalent to an existing FDA approved software as a medical device.

Artrya has requested this second meeting to validate and confirm the approach taken since the first Q-Sub meeting as a key final step in completing the FDA application process.

Artrya CEO Mathew Regan said: *"We have over the past 11 months diligently worked through the detailed program of activity determined with the FDA during our first Q-Sub meeting in June last year.*

"I have requested this second Q-Sub meeting to validate and confirm our approach. We will move into the submission process following the meeting with full confidence and increased certainty that we are on track for FDA approval expected during the second half of this year."

This announcement was approved by the Board.

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About Artrya

Based in Perth, Australia, Artrya was founded in 2018 with operations starting in early 2019. The Company was listed on the Australian Securities Exchange (ASX: AYA) in 2021.

Artrya is an applied artificial intelligence healthcare company that works alongside clinicians to improve the diagnosis of coronary heart disease and develop a holistic overview of at-risk patients. The company has developed deep-learning algorithms pending regulatory submission for clearance and approval in the US that will serve to predict and prevent acute coronary events.

For more information, see www.artrya.com