

**K250151 Us2.ca**Jun 20, 2025  
150 days to decisionK250151 · Product code: **SDJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250151/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiac Amyloidosis Status Indicator (SDJ)
Date received	Jan 21, 2025
Decision date	Jun 20, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eko.Ai Pte Ltd. D/B/A Us2.Ai</b>
Location	Singapore, SG
Contact	Hui Qun Tay
510(k) history	3 submissions · 3 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250151/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026