

K243866 InVision Precision Cardiac AmyloidMay 21, 2025
155 days to decisionK243866 · Product code: **SDJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k243866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiac Amyloidosis Status Indicator (SDJ)
Date received	Dec 17, 2024
Decision date	May 21, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Invision Medical Technology Corporation
Location	Los Angeles, CA, US
Contact	David Ouyang
510(k) history	2 submissions · 2 cleared · 2024-2025

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