

**K253801 ECG-AI Cardiac Amyloidosis (CA) 12-Lead Algorithm (1040)**

Apr 7, 2026  
130 days to decision

K253801 · Product code: **SHP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253801/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Nov 28, 2025
Decision date	Apr 7, 2026
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Anumana, Inc.</b>
Location	Cambridge, MA, US
Contact	Vyaas Shankar
510(k) history	5 submissions · 5 cleared · 2023-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k253801/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026