

K251293 CardioVisionNov 21, 2025
210 days to decisionK251293 · Product code: **QUO** · CardiovascularSource: <https://www.510kdatabase.net/k251293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Heart Failure Status Indicator (QUO)
Date received	Apr 25, 2025
Decision date	Nov 21, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icardio.Ai
Location	Los Angeles, CA, US
Contact	Roman Sandler
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251293/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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