FDA 510(k) Premarket Notification

K251293 CardioVision

CLEARED

Nov 21, 2025
210 days to decision

K251293 · Product code: **QUO** · Cardiovascular
Source: 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