FDA 510(k) Premarket Notification

K252589 Corvair Monza

CLEARED

Jan 9, 2026
147 days to decision

K252589 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k252589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 15, 2025
Decision date	Jan 9, 2026
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AliveCor, Inc.**
Location	San Francisco, CA, US
Contact	Samip Shah
510(k) history	19 submissions · 19 cleared · 2012-2026