FDA 510(k) Premarket Notification

CLEARED

K252533 HemoSphere Alta Advanced Monitoring Platform (ALTAALL1

Dec 18, 2025
128 days to decision

K252533 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k252533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 12, 2025
Decision date	Dec 18, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ALTACR1; ALTASR1)

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Niharika Mirji
Website	http://www.edwards.com
510(k) history	20 submissions · 19 cleared · 2011-2026

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...