FDA 510(k) Premarket Notification

K232294 HemoSphere Alta Advanced Monitoring Platform

CLEARED

Oct 31, 2023
91 days to decision

K232294 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k232294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 1, 2023
Decision date	Oct 31, 2023
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HemoSphere Alta™ Advanced Monitor (Smart Recovery); HemoSphere Alta™ Advanced Monitor (Cardiac); HemoSphere Alta™ Advanced Monitor (All-on-One)

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Varad Raghuwanshi
Website	https://www.edwards.com
510(k) history	135 submissions · 129 cleared · 1979-2026

Edwards Lifesciences, LLC is a global structural heart innovation company headquartered in Irvine, California. The company specializes in advanced medical devices for cardiovascular disease management. Edwards Lifesciences has established a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1979. The company's portfolio is dominated by Cardiovascular devices, which represent 88% of all submissions. The latest clearance was received in 2026, demonstrating continued active development and regulatory engagement. Recent clea...