CLEARED

K223865 HemoSphere Advanced Monitor, HemoSphere ClearSight Module, Acumen Assisted Fluid Management software feature with Acumen AFM Cable and Acumen IQ fluid meter, Pressure Controller, Heart Reference Sensor

Jun 9, 2023
168 days to decision

K223865 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k223865/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 23, 2022
Decision date	Jun 9, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Sara Pesian
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...