

K231035 FusedCO Algorithm

Jul 12, 2023
92 days to decisionK231035 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k231035/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 11, 2023
Decision date	Jul 12, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Omar Becerra
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...