FDA 510(k) Premarket Notification

CLEARED

K100709 EV1000 PLATFORM MODEL: EV1000A, EV1000DB, EV1000M

Dec 7, 2010
270 days to decision

K100709 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k100709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Mar 12, 2010
Decision date	Dec 7, 2010
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	PATRICIA MILBANK, JD
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k100709/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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