

**K103094 VIGILEO ARTERIAL PRESSURE CARDIAC OUTPUT /
OXIMETRY MONITOR**May 17, 2011
210 days to decisionK103094 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k103094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Oct 19, 2010
Decision date	May 17, 2011
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary
Other names	VIGILEO APCO / OXIMETRY MONITOR

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	MARGUERITE THOMLINSON
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.netDevice record: <https://www.510kdatabase.net/k103094/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026