FDA 510(k) Premarket Notification

CLEARED

K060660 EW200 SYSTEM (OXYGEN SATURATION MONITORING SYSTEM) AND PRESEP OXIMETRY CATHETER

Apr 25, 2006
43 days to decision

K060660 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k060660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Mar 13, 2006
Decision date	Apr 25, 2006
Days to decision	43 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	PAULA A TORRIANNI
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...