FDA 510(k) Premarket Notification

CLEARED

K160552 EV1000 Clinical Platform with ClearSight Finger Cuff or ClearSight System, EV1000 Clinical Platform

Jun 1, 2016
93 days to decision

K160552 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k160552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 29, 2016
Decision date	Jun 1, 2016
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Tara Viviani
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...