FDA 510(k) Premarket Notification

CLEARED

K190205 HemoSphere Advanced Monitor, HemoSphere Tissue Oximetry Module

Aug 29, 2019
206 days to decision

K190205 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k190205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 4, 2019
Decision date	Aug 29, 2019
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Chirag Shah
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...