

K163381 HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry CableApr 14, 2017
134 days to decisionK163381 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k163381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 1, 2016
Decision date	Apr 14, 2017
Days to decision	134 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...

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Device record: <https://www.510kdatabase.net/k163381/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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