

**K211465 HemoSphere Advanced Monitor, Viewfinder Remote,
HemoSphere Advanced Monitoring Platform**Jul 8, 2021
58 days to decisionK211465 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k211465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 11, 2021
Decision date	Jul 8, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences
Location	Irvine, CA, US
Contact	Chirag Shah
510(k) history	1 submissions · 1 cleared · 2021-2021

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