

**K201446 HemoSphere Advanced Monitoring Platform,
HemoSphere ClearSight Module**Oct 1, 2020
122 days to decisionK201446 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k201446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 1, 2020
Decision date	Oct 1, 2020
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Varad Raghuwanshi
510(k) history	2 submissions · 2 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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