

**K223127 HemoSphere Advanced Monitoring Platform,
HemoSphere ForeSight Oximeter cable**Nov 7, 2022
35 days to decisionK223127 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k223127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Oct 3, 2022
Decision date	Nov 7, 2022
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Michelle Ducca
510(k) history	3 submissions · 3 cleared · 2019-2022

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