

**K183646 Acumen Hypotension Prediction Index – EV1000
 Clinical Platform, Acumen Hypotension Prediction Index –
 HemoSphere Advanced Monitoring Platform, Acumen
 Hypotension Prediction Index – HemoSphere Advanced
 Monitoring Platform - Pressure**

May 21, 2019
 146 days to decision

K183646 · Product code: **QAQ** · Cardiovascular
 Source: <https://www.510kdatabase.net/k183646/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Predictive Cardiovascular Indicator (QAQ)
Date received	Dec 26, 2018
Decision date	May 21, 2019
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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