

K203224 Acumen Hypotension Prediction Index, HemoSphere Advanced Monitoring Platform

Jul 30, 2021
270 days to decisionK203224 · Product code: **QAQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k203224/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Predictive Cardiovascular Indicator (QAQ)
Date received	Nov 2, 2020
Decision date	Jul 30, 2021
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Lisa Gilman
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...

CLINICAL EVIDENCE - NCT03805217

Hypotension Prediction Index Study (HPI Study)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	485 patients (actual)
Study sites	11 sites
Condition studied	Hypotension
Study type	Observational
Completion date	Mar 17, 2020
Sponsor	Edwards Lifesciences (Industry)

Primary outcome

Reduction of Intraoperative Hypotension

Secondary outcome

Intraoperative Hypotension in Each Subject

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03805217